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(71) Applicant: TRITEC INDUSTRIES, INC. [US/US]; 185 Silas Deane Highway, Wethersfield, CT 06109 (US).

(72) Inventors: SIERACKI, Leonard, M. ; 9421 Kilimanjaro Road, Columbia, MD 21045 (US). DURKAN, Gerald, D. ; 27th Street and Robin Avenue, Altoona, PA 16603 (US). CHEN, Kevin, C.S. ; 9015 1st Street, Lanham, MD 20706 (US).

(74) Agents: BURNAM, Warren, H., Jr. et al.; Griffin, Branigan & Butler, P.O. Box 2326, 775 So. 23rd Street, Arlington, VA 22202 (US).

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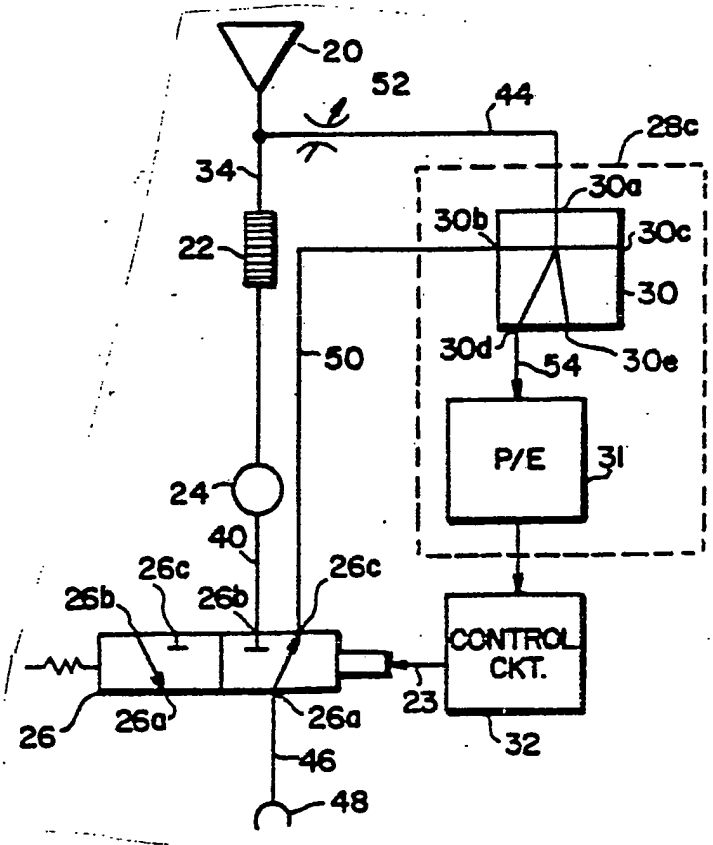
(57) Abstract

Respirating gas supply methods and apparatus designed to prevent overoxygenation and apnea event caused by occlusion or obstruction in the upper airway passages including a control circuit (32) responsive to a sensor (28) and operating a valve means (26) to supply pulses of respirating gas through a single hose cannula (48) to an in vivo respiratory system when negative pressure indicative of inspiration is sensed by the sensor (28). The control circuit (32) operates the valve (26) to communicate the in vivo respiratory system with a supply of gas (20) only if the negative pressure sensed by the sensor (28) does not occur within a predetermined yet selectively variable required minimum delay interval between successive pulsed applications of gas to the in vivo respiratory system. The pulse of gas applied to the in vivo respiratory system can be spiked pulses or square pulses. Humidifiers (62), nebulizers (70), and sources of a second gas (120, 268) are provided in accordance with various embodiments. Upon the detection of an appropriate apnea event, respirating gas supply apparatus according to various embodiments supply stimulus to the upper airway passages of an in vivo respiratory system in an effort to dislodge any occlusion or obstruction in the upper airway passages. In one embodiment the stimulus applied is a high pressure pulse of gas via line (144, 250). In another embodiment an electrical signal is applied to an electromyographic electrode (270) positioned in proximity to a nerve controlling a muscle or organ which may



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RESPIRATING GAS SUPPLY METHOD AND APPARATUS THEREFOR

BACKGROUND

This invention pertains to apparatus and methods for providing supplemental respirating gas, such as oxygen, to an in vivo respiratory system, and to methods of operating respirating gas supply apparatus so that apnea events caused by the occlusion of upper airway passages in the in vivo respiratory system are remedied.

United States patent application Serial No. 210,654, filed 26 November 1980 by Gerald P. Durkan and commonly assigned herewith, is incorporated herein by reference as illustrating a method of supplying respirating gas wherein a dose or pulse of gas is supplied to an in vivo respiratory system substantially at the beginning of inspiration. United States patent application Serial No. 210,654 also discloses a primarily fluidically-operated apparatus comprising a demand gas circuit. The fluidic apparatus comprising the demand gas circuit carries out the method described above and, by virtue of the method, is significantly smaller and more compact than other demand gas-type apparatus which supply respirating gas essentially

throughout the duration of inspiration. While this fluidic apparatus has proven extremely effective in such products as home oxygen concentrators and oxygen dillusion or delivery systems, for example, a further reduction in overall apparatus size would further enhance the utility of such products.

Many devices, including those depicted in United States patent application Serial No. 210,654, are adapted to monitor or sense pressure direction in an in vivo respiratory system throughout the respiratory cycle and to selectively supply gas in accordance with the pressure direction in the in vivo respiratory system. In this respect, the in vivo respiratory system creates a negative pressure upon inspiration and create positive pressure upon exhalation. In certain instances it is advantageous to supply pulses of gas such as these described in the application Serial No. 210,654 but in such a manner that a pulse is not necessarily supplied for every detection of negative pressure in the in vivo respiratory system. For example, should the in vivo respiratory system attempt to inspire too frequently, an apparatus operating strictly in the manner described in United States patent application Serial No. 210,654 would in some instances cause the in vivo respiratory system to overoxygenate. While breathing rate control circuits and override circuits have been disclosed in the prior art (such as U.S. patents 4,206,754 to Cox and 4,141,754 to Ismach, for example) these circuits are incompatable with the device described in the referenced application.

United States patent application Serial No. 210,654 also illustrates the usage of a "split" or "double hose" cannula which interfaces the in vivo respiration system through the nares with the sensing

and gas supply elements of the apparatus disclosed therein. Although the apparatus performs superbly using the double hose cannula, employment of a single hose cannula rather than a double hose cannula would enable both the sensing of the pressure direction in the in vivo respiratory system and the delivery of respirating gas to the in vivo respiratory system to be accomplished through the same hose. Single hose cannulae, being less expensive to manufacture and more convenient for the physician and user, are generally more prevalent on the market than double hose cannula. Thus, it would be advantageous to adapt systems such as that disclosed in the referenced application for compatibility with a single hose cannula.

Moreover, it is generally preferable to humidify respirating gas before supplying the gas to an in vivo respiration system. In some circumstances it is desirable to nebulize the respirating gas with medication before supplying the gas to the in vivo respiration system. Although humidifiers and nebulizers have long been used with oxygen supply systems, it is not evident from the prior art how a humidifier or nebulizer can be appropriately utilized with apparatus such as those described in United States patent application Serial No. 210,654, especially if apparatus of that type are used with a single hose cannula as discussed above. A great danger in utilizing humidifiers and/or nebulizers with either single or double hose cannula systems is the transfer of moisture through the hose leading to sensing means used to determine the direction of pressure in the in vivo system. Moisture in the hose leading to the sensing means contaminates the sensor and tends to considerably shorten the life of the sensor.

In some situations it may also be desirable to supply another gas, such as an anesthetic gas, to in vivo respiratory system along with the supply of respirating gas. In such situations, the dosage of second gas must usually be in controlled relation to the amount of respirating gas supplied simultaneously therewith. Moreover, a serious problem results in a demand gas-type device when medicating gas is continually applied regardless of the ability or inability of the in vivo system to demand the respirating gas.

United States patent 4,414,982, filed 26 November 1980 by Gerald P. Durkan and commonly assigned herewith, is incorporated herein by reference as disclosing a respirator apparatus including a predominately fluidically operated apnea event circuit which signals the occurrence of an apnea event after the lapse of a predetermined time interval since the last inspiration attempted by an in vivo respiratory system. One cause of apnea events such as those detected by the apparatus of United States patent 4,414,982 is the occlusion of upper airways, such as the oropharyngeal airway, in the in vivo respiratory system.

In the above respect, it has been suggested by Remmers et al. ("Pathogenesis of Upper Airway Occlusion During Sleep", Journal of Applied Physiology 1978; 44:931-38) that in some in vivo respiratory systems the subatmospheric or negative pressure occasined during inspiration sucks the tongue and soft palate against the posterior oropharyngeal wall. Other causes and conditions associated with upper airway obstruction/occlusion are summarized by Sullivan et al. ("Reversal of Obstructive Sleep Apnoea By Continuous

Positive Airway Pressure Applied Through The Nares", The Lancet, April 18, 1981, pp. 862-865) which is incorporated herein by reference for a discussion of the obstruction/occlusion phenomena. Sullivan et al. report treatments for obstructive sleep apnoea syndrome wherein low levels of pressure (in the range of 4.5 to 10 cm water) were continuously applied to provide a pneumatic splint for the nasopharyngeal airway.

United States patent 4,155,356 to Venegas discloses a respiration assisting method and apparatus comprising means for generating a series of pressure pulses and means for transmitting the pressure pulses to air passageways in the lungs. The transmission means comprises a tube placed in the trachea so that pressure waves created by the pressure pulses outward displace walls of collapsed air passageways in the lungs and maintain such outward displacement during expiration. Venegas provides no means for the sensing of conditions in the lungs nor does he coordinate the application of pressure pulses in time relation with the occurrence of such conditions.

In view of the foregoing, it is an object of this invention to provide a respirating gas supply apparatus which, upon the detection of an appropriate apnea event caused by the occlusion or obstruction of upper airway passages in an in vivo respiratory system, attempts to remedy the occlusion or obstruction in the upper airway passages.

It is an object of the present invention to provide a demand respirating gas supply method and apparatus which prevents overoxygenation by supplying a fixed volume dose of respirating gas per unit time to an in vivo respiratory system.

An advantage of the invention is the provision of a demand respirating gas supply method and apparatus which employs a single hose cannula, thereby allowing pressure sensing and gas supply to be accomplished through the same line.

A further advantage of one embodiment of the invention is the provision of a method and apparatus for supplying spiked shaped pulses of gas at the beginning of an inspiration.

An advantage of another embodiment of the invention is the provision of a method and apparatus for supplying square shaped pulses of gas at the beginning of an inspiration.

Yet another advantage of the invention is the provision of a compact respirating gas supply apparatus.

Still another advantage of the invention is the employment of humidifiers, nebulizers, and the like without deleterious impact upon a sensor used in a respirating supply gas apparatus.

SUMMARY

In various embodiments of a respirating gas supply method and apparatus, a control circuit responsive to a sensor operates a valve to supply doses or pulses of respirating gas through a single hose cannula to an in vivo respiratory system when negative pressure indicative of inspiration is sensed by the sensor. The control circuit operates the valve to communicate the in vivo respiratory system with a supply of gas only if the negative pressure sensed by the sensor does not occur within a predetermined yet selectively variable required minimum delay inverval between successive pulsed application of the gas to the in vivo respiratory system.

In some embodiments, a three-way valve having ports connected to the sensor, the gas supply, and the single hose cannula is used. In another embodiment, a four-way valve facilitates usage of the apparatus in conjunction with a humidifier and/or a nebulizer.

In one embodiment a respirating gas supply apparatus has a sensor comprising a biased fluidic amplifier and a pressure-to-electric (P/E) switch.

Apparatus according to the embodiments described herein can be operated to supply spiked pulses or square pulses of gas depending on whether a flowmeter is connected between the supply of gas on the valve.

The control circuit of the respirating gas supply apparatus also has means for determining if the in vivo respiratory system has failed to demand a pulse of gas after the elapse of a predetermined but selectively variable maximum time inverval. Upon detecting such an apnea event, the apparatus activates various indicator or alarm means and operates the valve to supply an additional pulse or pulses of gas to the in vivo respiratory system.

Upon the detection of an appropriate apnea event, respirating gas supply apparatus according to various embodiments supply stimulus to the upper airway passages of an in vivo respiratory system in an effort to dislodge any oclusion or obstruction in the upper airway passages. In one embodiment the stimulus applied is a high pressure pulse of gas. In another embodiment an electrical signal is applied to an electromyographic electrode positioned in proximity to a nerve controlling a muscle or organ which may obstruct the upper airway passage.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and other objects, features and advantages of the invention will be apparent from the following more particular description of the preferred embodiments of the invention, as illustrated in the accompanying drawings in which like reference characters refer to the same parts throughout different views. The drawings are not necessarily to scale, emphasis instead being placed upon illustrating the principles of the invention.

Fig. 1A is a schematic diagram showing a gas supply apparatus according to an embodiment of the invention wherein gas is supplied in a spiked pulse mode;

Fig. 1B is a schematic diagram showing a gas supply apparatus according to an embodiment of the invention wherein gas is supplied in a square pulse mode;

Fig 1C is a schematic diagram showing a gas supply apparatus according to an embodiment of the invention wherein sensing means comprises a fluidic amplifier;

Fig. 2 is a schematic diagram showing a gas supply apparatus according to an embodiment of the invention wherein supply gas is humidified;

Fig. 3 is a schematic diagram showing a gas supply apparatus according to another embodiment of the invention wherein supply gas is humidified;

Fig. 4A is a graph illustrating a spiked pulse method of supplying gas according to a mode of the invention;

Fig. 4B is a graph illustrating a square pulse method of supplying gas according to a mode of the invention;

Fig 5 is a schematic diagram showing a control means according to an embodiment of the invention;

Fig. 6 is a schematic diagram showing a gas supply apparatus according to another embodiment of the invention wherein a second gas is also supplied;

Fig. 7A is a plan view of a fluid amplifier of the embodiment of the gas supply apparatus of Fig. 1C;

Fig. 7B is a graph illustrating the output pressure gain curve for the fluidic amplifier shown in Fig. 7A; and,

Figs. 8A, 8B, and 8C are schematic diagrams showing differing embodiments of gas supply apparatus which detect apnea events and attempt to remedy apnea events caused by occlusion of upper airway passages in the in vivo respiratory system.

DETAILED DESCRIPTION OF THE DRAWINGS

The respirating gas supply system of the embodiment of Fig. 1A comprises a source of gas 20; a flowmeter 22; a fluidic capacitance 24; valve means 26; sensing means 28; and, control means 32.

Source 20 is typically a source of oxygen gas. Depending upon the particular environment of use, source 20 may be a portable tank or a wall supply, for example. Source 20 is connected by line 34 to the flowmeter 22. As used herein unless otherwise indicated, any fluid conveying means, such as a duct, pipe, channel, or other closed fluid conduit, is referred to as a line.

While the flowmeter 22 may be of any conventional type, a ball float-type flowmeter manufactured by Dwyer is suggested as one acceptable model. The flowmeter illustrated in Fig. 1A comprises a needle valve (not shown) which has an inherent resistance FR to the flow of gas. The flowmeter

inherent resistance is dependent, inter alia, on the dimensions of the needle valve and the needle orifice. The flowmeter 22 is connected to the capacitance by line 40.

Capacitance 24 is shown as a tank but in another embodiment is merely a relatively long length of tubing. As seen hereinafter, the volume of capacitance 24, the flowmeter inherent resistance FR, the inherent resistance VR of the valve 26, and the interrelationship between these factors influence the amplitude of a pulse of gas produced by the respirating gas supply system of Fig. 1A.

The valve means 26 of the embodiment of Fig. 1A is a three-way two position solenoid-actuated spool valve having ports 26a, 26b, and 26c in its bore. Port 26a is connected by line 46 (a single hose) to a means 48 for applying gas to an in vivo respiratory system. Although the particular means shown in Fig. 1A is a single hose cannula, it should be understood that other suitable devices, such as an endotrachial tube or a hand resuscitator, for example, may be employed. The aforesaid line 40 ultimately connects port 26b to the source 20. Port 26c is connected by line 50 to the sensing means 28.

As shown in the Fig. 1 representation of the valve 26, the spool of valve 26 is biased to its first position to connect port 26a to port 26c so that the cannula 48 (and hence in vivo respiratory system (not shown) including nares in which the cannula 48 is inserted) is in fluidic communication with the sensing means 28. It should be understood that the valve 26 can be operated to move the spool to its second position to connect port 26a with port 26b so that a pulse of gas is suppled to the in vivo respiratory system through the single hose 46. When connected in this manner, the valve 26 has an inherent resistance VR

to the flow of gas which is dependent on the size of the orifice connecting port 26a to port 26b.

The valve 26 is electrically controlled by control means 32 in the manner hereinafter described. While the valve 26 shown in Fig. 1A is of a type manufactured by Lee as model LFAA 1200318H, any comparable model can be used.

The sensing means 28 of Fig. 1 comprises suitable means for sensing a negative fluidic pressure applied along line 50 and for generating an electrical signal in accordance with the sensing of the negative fluidic pressure. In one embodiment the sensor 28 comprises a pressure-to-electric (P/E) switch, such as a Model E P/E Switch manufactured by the Dietz Company which can sense pressures as low as 0.02 inches (column of water). In this embodiment, the negative input port of the P/E switch is connected to the line 50 while the positive input port is left open to ambient. Large diaphragms used in state-of-the-art P/E switch technology, such as the two inch diameter diaphragm of the Dietz Model E P/E, have considerable internal volume and hence, for some environments of use, a significantly long time response. Many P/E switches must also be mounted horizontally to achieve maximum sensitivity, but mounting the switches horizontally presents another problem -- acceleration sensitivity of the diaphragm.

The sensing means 28C of Fig. 1C comprises means 29 for sensing positive fluidic pressure and for generating an electrical signal in accordance with the sensed fluidic pressure, as well as amplification means such as fluid amplifier 30. The fluid amplifier 30 depicted in Fig 1C is a biased turbulent proportional amplifier shown in more detail in Fig. 7A.

The biased fluidic amplifier 30 has a power input stream 30; two control ports 30b and 30c; and,

two output ports 30d and 30e. The power stream input port 30a is connected by the line 44 ultimately to the source 20. A variable restrictor 52 on line 44 is used to limit the magnitude of flow and pressure of flow of the input stream and thus the sensitivity of the fluidic amplifier 30. Control port 30b is connected by line 50 to port 26c of the valve 26 such that negative pressure in line 50 (created by inspiration in the in vivo respiratory system) deflects the power stream to output port 30d. The amplifier 30 is biased such that non-negative pressure in line 50 results in the power stream passing through the output port 30e.

The amplifier structure of Fig. 7A illustrates the biased nature of the amplifier 30. The amplifier 30 is configured with an off-set splitter. That is, the power input stream 30a is canted so that, absent control signals at ports 30b (also labeled C_R) and 30c (C_L), the output is normally biased to the left output port 30e (L). When negative pressure is applied through port 30b, the output switches to port 30d. When the negative pressure ceases, the output automatically switches back to port 30e. In a preferred embodiment the amplifier 30 operates with a low power supply so that the jet is laminar. The output pressure gain curve for the fluid amplifier 30 of Fig. 7A is shown in Fig. 7B.

A fluidic amplifier of the type manufactured by TriTec, Inc. as Model No. AW12* functions well as the amplifier 30 of Fig. 7A to give a sensitivity to negative pressures at least as low as 0.02 cm water, but for the use shown, especially considering the operating perameters of the P/E switch 31, a sensitivity of approximately 0.5 cm water is sufficient. It should be understood by those skilled in the art that other fluidic elements, such as a NOR gate, can be configured with the circuitry shown to yield acceptable results.

In the embodiment of Fig. 1C a pressure-to-electric (P/E) switch 31 is used as the means for sensing positive pressure and for generating an electrical signal in accordance with the sensed fluidic pressure. The P/E switch 31 illustrated in Fig. C is a conventional P/E switch such as that manufactured by Fairchild as Model PSF 100A. The positive input port of the P/E switch 31 is connected to the output port 30d of sensor 30 by line 54 while the negative input port thereof is open to ambient. For the particular sensing means 28 illustrated in Fig. 1C, the P/E switch 31 should be sensitive enough to switch when positive pressure as low as 0.5 inch of water is incident thereon. When P/E switch 31 receives such pressure, P/E switch 31 closes a switch 36 as seen hereinafter with reference to Fig. 5.

Referring now again to the embodiment of Fig 1A, it should be understood that other types of sensing means 28 may be employed. Those skilled in the art recognize that (if operating requirements permit) a thermistor system can be utilized, provided the thermistor system is made direction sensitive (by utilizing two thermistors and appropriate time delay measurement circuitry). Ordinarily, however, the flow-type (as opposed to pressure-type) sensitivity of a thermistor prevents the thermistor from sensing flow rapidly enough to facilitate the supply of an oxygen pulse early in inspiration, such as in the manner taught in U.S. patent application Serial No. 210,654. In another embodiment, a pressure transudcer functions as the sensing means 28. The pressure transducer can be a solid state, a capacitance, or an electro-mechanical (diaphragm-type) transducer, depending on the sensitivity required. Transducers provide an analog signal and require rather complex electrical circuitry. A suitable solid state crystal may someday be developed to function as the sensing means 28 in

accordance with desired sensitivity requirements.

The respirating gas supply system of Fig. 1B resembles the system of Fig. 1A but does not have the flowmeter 22. As seen hereinafter, the system of Fig. 1A produces a spiked pulse of gas whereas the system of Fig. 1B produces a square pulse of gas.

The respirating gas supply system of the embodiment of Fig. 2 basically resembles the system of Fig. 1B but, rather than employ a three-way valve, utilizes a four-way two-position valve 58 as its valve means. The four-way valve 58 has four ports in its bore: port 58a connected by the line 46 to the cannula 48; port 58b connected by line 42 ultimately to the source 20; port 58c connected by line 50 to control port 30b of sensor 28; and, port 58d connected by a line 60 to an input of a humidifier 62. Valve 58 can be any conventional four-way two position valve, such as the solenoid-actuated spool valve model 8345E1 manufactured by ASCO. As shown in the Fig. 2 representation of valve 58, the valve 58 is biased in a first position to connect port 58a to port 58c so that cannula 48 (and hence the in vivo respiratory system) is in fluidic communication with the sensor 28. It should be understood that the valve 58 can be actuated to a second position to connect port 58b to port 58d. When this occurs, gas is supplied through the valve 58 and line 60 to the input of humidifier 62.

Humidifier 62 is a bubble type humidifier, such as the model 003-01 humidifier available from Respiratory Care, Inc. Humidifier 62 yields a humidified gas flow on line 64 connected to the output of the humidifier 62. Line 64 connects with a line 46 at point 66. A variable resistance 64R on line 64 insures that upon inspiration the path of least resistance is through line 46 and the valve 58 rather than through line 46.

It should be understood that the apparatus of

the embodiment of Fig. 2 can be connected in the manner of Fig. 1A (that is, with a flowmeter) to operate in a spiked pulse mode rather than a square pulse mode.

The respirating gas supply system of the embodiment of Fig. 3 basically resembles the system of Fig. 1B but further incorporates the humidifier 62. A line 65 connects to line 46 at point 67. The line 65 connects the point 67 to the input of the humidifier 62. Line 64 from the output of the humidifier 62 terminates in a nozzle 68 of a venturi 70. The venturi 70 is connected on line 46 intermediate the port 58a of valve 58 and the cannula 48. A variable resistance 65R on line 65 insures that upon inspiration the path of least resistance is through the line 46 and the valve 26 rather than through line 65. Resistance 65R also serves to control the flow into the humidifier 62 through line 65. The venturi 70 shown is a type F-4417-10 available from Airlogic, although any comparable venturi is suitable. Again, it should be understood that the embodiment of Fig. 3 can, if desired, incorporate a flowmeter in order to operate in a spiked pulse mode.

It should be understood by those skilled in the art that a device for administering medication, such as a nebulizer, can be connected in the systems of Figs. 2 or 3 in essentially the same respective manners as the humidifier 62 shown therein.

The respirating gas supply apparatus of the embodiment of Fig. 6 basically resembles the embodiment of Fig. 1B but further includes means for suppling a second gas to the in vivo respiratory system. The apparatus of Fig. 6 further comprises a source 120 of a second gas (such as an anesthetic gas, for example), a capacitance 124; and, second valve means 126. Source 120 is connected to capacitance 124 by line 134; capacitance 124 is connected to the valve means 126 by

line 142. The apparatus of the embodiment of Fig. 6 can be used, if desired, with a humidifier in the manner described above with reference to either Fig. 2 or Fig. 3.

Valve 126 is a two-way two position solenoid-actuated spool valve having port 126a and 126b in its bore. The central spool of valve 126 is biased in a first position as shown in Fig. 6 so that ports 126a and 126b are not communicating. Port 126b of valve 126 is connected by line 144 to a point 146 where line 144 joins line 46. A variable resistance 147 on line 144 insures that upon inspiration the path of least resistance is through the line 46 and valve 26 rather than through line 144. The solenoid valve 126 is electrically connected by lines L3' and L3 to the control means 32. In other embodiments the solenoid valve is mechanically connected to a control means.

The control means 32 of the embodiment of Fig. 5 is suitable for use with apparatus constructed in accordance with any of the foregoing embodiments. Control means 32 is a circuit comprising four NAND gates (72, 74, 76, and 78); four NOR gates (80, 82, 84, and 86); three transistors (T1, T2, and T3); a 555 timer chip 88; a 556 dual timer chip 90; LEDs 92 and 94; piezo electric member 96; and, various resistances and capacitances as hereinafter designated.

As used with reference to Fig. 5, the notation "LX" denotes an electrical line (as opposed to a fluidic line) where X is a appropriate reference number. For example, controller 32 includes a line L1 connected to a high DC voltage supply (not shown) and line L2 connected to a low DC voltage supply (also not shown). The potential difference across L1 and L2 is between 12 and 15 volts DC.

The 556 dual timer chip 90 shown in Fig. 5 is a 14 pin chip manufactured by National Semiconductor as part number LM 556CN. It should be understood that any comparable 556 dual timer chip is suitable for the circuit of Fig. 5. For the particular chip shown, pins 1-7 correspond to pins of a first timer in the dual timer while pins 8-14 correspond to pins of a second timer. The pins are labeled as follows:

PIN DESCRIPTIONS FOR 556 CHIP

DESCRIPTION	TIMER 1	TIMER 2
discharge	1	13
threshold	2	12
control voltage	3	11
reset	4	10
output	5	9
trigger	6	8
ground	7	
operating voltage		14

The pin connections for the first timer of the 556 dual timer 90 are as follows: Pins 1 and 2 are connected to line L2 through a series combination of resistor R1 and a 100K variable potential resistance R2. Pins 1 and 2 are also connected to line L2 through capacitance C1. Pin 3 is connected to line L2 through capacitor C2. Pin 4 is connected directly to line L1. Pin 5 is connected to the base of transistor T1 through resistor R3. Pin 5 is also connected to the anode of LED 92 (the cathode of LED 92 being connected through resistor R4 to the line L2). Pin 6 is connected through capacitor C3 to the output terminal of NOR 80. Pin 6 is also connected to line L1 through the resistor R14 and to line L2 through the resistor R15. Pin 7 is connected directly to line L2.

The pin connections for the second timer of the 556 dual timer 90 are as follows: Pin 8 is connected through capacitor C4 to the output terminal of NOR 84, as well as to line L1 through the resistor R16 and to line L2 through the resistor R17. Pin 9 is connected to both input terminals of NAND 74. Pin 10 is connected directly to line L1 and to a point 102 discussed hereinafter. Pin 11 is connected through capacitance C5 to line L2. Pins 12 and 13 are connected to line L1 through a series combination of resistor R5 and a 100K variable potential resistor R6. Pins 12 and 13 are also connected to line L2 through capacitance C6. Pin 14 is connected directly to line L1.

The 555 timer chip 88 shown in Fig. 5 is an eight pin chip manufactured by National Semiconductor as part number LM 555CN. It should be understood that any comparable 555 chip is suitable for the circuitry of Fig. 5. For the particular chip shown the pins are labeled as follows:

DESCRIPTION	PIN
ground	1
trigger	2
output	3
reset	4
control	5
threshold	6
discharge	7
operating voltage	8

The pin connections for the 555 timer chip 88 are as follows: Pin 1 is connected directly to line L2. Pin 2 is connected to the output of NOR 82 and to the base of transistor T2. Pin 3 is connected to both

inputs of NOR 86 and to a point 98. Pin 4 is directly connected to line L1. Pin 5 is connected to line L2 through capacitor C7. Pins 6 and 7 are connected to line L2 through capacitance C8. Pins 6 and 7 are also connected to line L1 through a series combination of resistances, the combination including a resistor R7 and anyone of a group of parallel-arranged resistances such as resistances Ra, Rb, and Rc.... Which of the parallel-arranged resistances is used depends on the manual positioning of a switch 100 as described hereinafter. Pins 6 and 7 are also connected to the emitter of transistor T2. Pin 8 is connected directly to the line L1.

NAND 72 has a first input terminal 72a connected to line L1 through resistance R8 and connected to L2 through the switch 36. A second input terminal 72b of the NAND 72 is connected to the output terminal of NAND 74. The output terminal of NAND 72 is connected to a first input terminal 80a of NOR 80, as well as to both input terminals of the following: NOR 82, NOR 84, and NAND 76. The first input terminal 80a of NOR 80 is also connected to a point 104 intermediate the output terminal of NOR 86 and the anode of LED 94. The second input terminal 80b of NOR 80 is connected to line L2 through resistor R9. The lines L4, L5, L6, and L7 shown in Fig. 5 are connected to further devices, such as instrumentation which, unless otherwise noted herein, do not form part of the present invention.

Transistor T1 is a NPN transistor, such as the type available from GE as part GE-66A. The emitter of transistor T1 is connected directly to line L2. The collector of transistor T1 is isolated from line L2 by a diode D1 (IN 4005) and is connected to the positive terminal of appropriate valve means (such as valve 26 or valve 58) by line L3. Line L8 is connected to the

negative (or ground) terminal of the appropriate valve means.

Transistor T2 is a PNP transistor, such as the type available from GE as part GE -65. The emitter of transistor T2 is connected to pins 6 and 7 of timer 88. The base of transistor T2 is connected to the output of the NOR 82. The collector of the transistor T2 is directly connected to line L2.

Fig. 5 also includes an alarm circuit generally denoted as 100. A point 102 of alarm circuits 100 is connected both to line L1 and (through capacitor C9) to line L2. Terminal 96b of the piezo electric 96 is connected to point 102 through resistance R10 and to the base of transistor T3 through resistor R11. Terminal 96a of the piezo 96 is connected to point 102 through resistance R12. Terminal 96c of the piezo electric 96 is connected to point 98 and to the emitter of transistor T3. The alarm circuit 100, when activated, functions as an oscillator and drives therefor to produce audible oscillation. It should be understood that any conventional circuit, including buzzers and electro-mechanical alarms, may be utilized instead.

Transistor T3 is a NPN transistor, such as the type available from GE as part GE-66A. The collector of transistor T3 is connected through resistor R12 to the point 102. The other connections of the transistor T3 are described above.

The NOR gate 86 has its output terminal connected to the anode of the LED 94. The cathode of the LED 94 is connected through resistor 13 to the line L2.

Conventional NOR gates can be used for the NORs 80, 82, 84 and 86 and conventional NAND gates can be used for the NANDs 72, 74, 76 and 78 utilized in the controller of Fig. 5. For the embodiment of Fig. 5,

however, the NANDs illustrated are parts 4011B manufactured by National Semiconductor and the NORs are parts 4001B manufactured by National Semiconductor.

The suggested values for the resistances and capacitances for the embodiment of Fig. 5 are as follows:

RESISTANCES		CAPACITANCES	
R1=	10K	C1=	10μ
R2=	(variable)	C2=	0.02μ
R3=	1K	C3=	0.1μ
R4=	2K	C4=	0.1μ
R5=	10K	C5=	0.02μ
R6=	(variable)	C6=	22μ
R7=	1.2K	C7=	0.02μ
R8=	2K	C8=	220μ
R9=	20K	C9=	10μ
R10=	220K		
R11=	10K		
R12=	510		
R13=	2K		
R14=	1M		
R15=	1M		
R16=	1M		
R17=	1M		

In the operation of the respirating gas supply system of the embodiment of Fig. 1A, gas from the source 20 is passed through line 34 to the flowmeter 22. The needle valve (not shown) in flowmeter 22 is set to control the rate of flow through the flowmeter 22. Gas flowing through the flowmeter 22 continues through line 36 to the capacitance 24. From capacitance 24 the gas passes into line 42. The gas in line 42 does not pass through the valve 26 until the valve 26 is actuated so that port 26b thereof is

connected to port 26a in the manner hereinafter described.

The cannula 48 is inserted in the nares of an in vivo respiratory system. When a negative pressure is created by an attempted inspiration by the in vivo respiratory system, the negative pressure is applied to the single hose 46.

For the apparatus shown in the embodiment of Fig. 1A, valve 26 is normally in the position shown in Fig. 1A with port 26a connected to port 26c. Upon inspiration a negative pressure is created in line 50. In the embodiment described above wherein sensor 28 is a P/E switch, for example, the negative pressure in line 50 acts upon the negative pressure input port of the P/E switch. The P/E switch accordingly closes the switch 36 of Fig. 5.

For the apparatus shown in the embodiment of Fig. 1C, the negative pressure in line 50 created by inspiration is applied to the control port 30b of fluidic amplifier 30. The negative pressure at control port 30b causes the power stream input of amplifier 30 to be deflected so that output occurs at the output port 30d rather than at the output port 30e to which it is normally biased. The output from port 30d creates a positive fluid signal on line 54 which is applied to the positive input port P/E switch 31. The P/E switch 31 accordingly closes the switch 36 of Fig. 5.

With respect to the controller 32 as depicted in Fig. 5, the closing of switch 36 completes a circuit between lines L1 and L2 and causes a false signal to be applied to input port 72a of NAND 72. Since the input port 72b normally receives a true signal (except when the negative pressure is sensed during a required minimum delay interval after the next preceeding application of gas in the manner hereinafter described), the output of NAND 72 is true.

Accordingly, input terminal 80a of NOR gate 80 goes true. Likewise, all input terminals of NAND 76, NOR 82, and NOR 84 are true.

Unless an apnea event is detected as hereinafter described, or unless a true signal is received on line L4, the input terminal 80b is false. At this point, the output of NOR gate 80 is false. The output of NOR 84 is also false.

False outputs from the NOR gates 80 and 84 are applied to pins 6 and 8 of the dual timer 90. Pin 6 is the trigger input of the first timer included in the dual timer 90; pin 8 is the trigger input of the second timer included in the dual timer 90. As result of trigger pins 6 and 8 going from true to false, the outputs from corresponding pins 5 and 9 go true.

Output pin 5 of the dual timer 90 going true causes transistor T1 to conduct, so that a current is established on line L3. The resultant electrical signal on line L3 causes the solenoid valve 26 to move from its normally biased position as shown in Fig. 1A to its second position where port 26b thereof is connected to port 26a.

Connecting port 26b of the solenoid valve 26 to port 26a enables the gas in line 42 to be transmitted through the valve 26. It should be recalled that both the flowmeter 22 and the valve 26 have inherent resitances to the flow of gas. The resistance FR of the flowmeter is generally greater than the resistance VR of the valve 26. Thus, as the valve 26 moves to connect port 26a to ports 26b, pressure in line 42 drops and, if the valve 26 remains in this position long enough, the rate of flow of the gas eventually is dictated by the resistance FR of the flowmeter 22.

Valve 26 thus allows a pulse of gas to pass from line 42 through valve 26, through line 46 and

cannula 48, and into the in vivo respiratory system. As seen hereinafter, the duration of the pulse is determined by the length of the time the valve 26 remains in the position wherein port 26b is connected to port 26a. The amplitude of the pulse is a function of the flow rate through the valve 26. Incorporation of the flowmeter 22 and to the fluid supply circuit of Fig. 1A causes the pulse of gas produced to have a spike shape such as that shown in Fig. 4A. While the pulse of gases is being supplied, the LED 92 conducts to provide a visual indication of the same since the signal applied to transistor T1 is also applied to the LED 92 anode.

When the output pin 5 of the dual timer 90 goes false the pulse of gas supplied through the valve 26 is caused to terminate. In this respect, a false signal from pin 5 stops the transistor T1 from conducting, so that the signal on line L3 goes false. A false signal on line L3 causes the solenoid valve 26 to return to its normally biased position as shown in Fig. 1A.

The time at which the output pin 5 of dual timer 90 goes false depends on the voltage value supplied to pin 2 of the dual timer 90. The voltage value at pin 2 of the dual timer 90 is dependent on the value chosen for the 100K variable potential resistor R2. In this respect, the pulse of gas is supplied until the voltage at pin 2 becomes two-thirds of the voltage difference seen across pins 7 and 14. For the embodiment described herein with reference to the circuit values mentioned above, when the resistance value of resistor R2 is 35K, for example, a pulse of 0.5 seconds duration will be supplied.

As mentioned above, both timers in the dual timer 90 were triggered so that the output pins 5 and 9 became true. A true signal on pin 5 moved the solenoid

valve 26 as described hereinbefore. A true on pin 9, however, causes the NAND gate 74 to go false, so that a false signal is supplied to the input terminal 72b of NAND 72. The output of NAND 72 thus goes true and remains true as long as pin 9 of the dual timer 90 is true.

While the output of NAND 72 remains true, pin 6 of the dual timer 90 cannot be triggered false. In this respect, pin 6 of the dual timer 90 remains false and cannot transition from true to false while pin 9 is true. This means that should the in vivo respiratory system attempt to inspire while pin 9 of dual timer 90 is still true, the attempted inspiration will have no effect on pin 6 of the dual timer 90, and hence no effect on the valve 26 so that an additional pulse of gas is not supplied. Further attempted inspirations are ineffectual until the output pin 9 of dual timer 90 goes false. The time at which the output pin 9 of dual timer goes false is selectively variable by the value chosen for the 100K potential variable resistor R6. R6 affects the voltage value applied to the threshold pin 12 of the dual timer 90, which determines when the output pin 9 goes false.

The value chosen for the resistor R6 determines a required minimum interval between successive applications of gas to the in vivo respiratory system. This enables the apparatus to supply a fixed volume dose of respirating gas to the in vivo respiratory system per unit time. For the suggested circuit values given hereinbefore, resistor R6 chosen to have a value of 73K gives a delay interval of 2.0 seconds. That is, when a negative pressure is sensed in the in vivo respiratory system, controller 32 will not permit a pulse of gas to be applied to the in vivo respiratory system unless the required delay interval has elapsed since the sensing of negative

pressure which resulted in the next preceding application of gas to the in vivo respiratory system. In this manner, the in vivo respiratory system is protected from over oxygenation should the in vivo respiratory system attempt an abnormally true number of inspirations. Without this protection feature, the in vivo respiratory system would dangerously be supplied excess pulses of gas when attempted inspirations are too frequent.

The foregoing method of requiring the elapse of a minimum delay interval between successive applications of gas to the in vivo respiratory system also enables the apparatus of the embodiment discussed herein to be operated when desired in accordance with the method described in U.S. patent application Serial Number 210,654, already incorporated herein by reference. The pulse has a duration which can be less than the duration of the inspiration.

When the apparatus of the embodiment of Fig. 1A, for example, is operated in accordance with a mode of the method of patent application Serial Number 210,654, the valve 26 returns to its normally biased position with port 26a connected to port 26c long before the negative pressure in the in vivo respiratory system has ceased. In this respect, the pulse of gas is supplied for a time period which is a fraction of the duration of inspiration. Without the protective function of the second timer (and the effect of output pin 9 of the dual timer 90 on NAND 80 to prevent trigger pin 6 of the dual timer 90 from going from true to false), an additional pulse of gas would be supplied for the same inspiration. Thus, the protective function provided by the second timer of the dual timer 90 of controller 32 allows the valve 26 to return to its normally biased position and provides a buffer time interval in which the valve 26 cannot again be

actuated. Thus, controller 32 facilitates the usage of a single simple valve rather than a series of valves. Moreover, controller 32 and the valve means associated therewith facilitates the use of a single hose 46 leading to a single hose cannula 48, which allows both negative pressure and positive pressure to be transmited through the same line 46.

The operation of the embodiment of Fig. 1B basically resembles that of the embodiment of Fig. 1A, but, rather than supplying a spiked pulse, the embodiment of Fig. 1B supplies a square pulse such as that shown in Fig. 4B. The square pulse results from the fact that there is no flowmeter in the line connecting the source 20 the the valve 26. Thus, the pressure in the capacitance 24 -- whether it be merely a length of tubing or a tubing and a tank -- is the pressure of the source 22 rather than the pressure determined by the inherent resistance of the flowmeter. Thus, when valve 26 is opened to connect port 26a and port 26b, the only limiting influence on the flow of gas is the inherent resistance of the valve 26. Without the inherent resistance FR of the flowmeter to dampen the pulse, the pulse assumes a square shape. It is currently thought that the square shape mode allows a more accurate dosage of volume flow to the cannula 48.

The operation of the embodiment of Fig. 2 also basic resembles that of Fig 1A but further supplies a humidified pulse of gas to the in vivo respiratory system. In the same manner described with reference to the Fig. 1A embodiment, controller 32 causes valve 58 to move to a position where a port 58b communicates with port 58d when an appropriate negative pressure is detected in the in vivo respiratory system. A pulse of gas then passes through line 60 to humidifier 62. A humidified pulse of gas leaves

humidifier 62 and travels to the in vivo respiratory system on line 64 and 46. In this manner moisture provided by the humidifiers 62 does not contaminate ports 58a and 58c of valve 58, nor the sensor 28 connected thereto by line 50.

It should be apparent by the operation of the embodiment of Fig. 1A that the operation of the embodiment of Fig. 3 is substantially the same except that in the Fig. 3 embodiment the pulse of gas is also humidified by humidifier 62 before it passes to the in vivo respiratory system. The pulse of gas leaves the valve 26 through line 46. A point 67 the pulse divides so that a pulse first portion continues to travel on line 46 to the input of venturi 70 and a pulse second portion is supplied on line 65 to the input of the humidifier 62. The resulting humidified gas from the humidifier 62 is applied on line 64 to nozzle 68 of the venturi 70. The pulse of gas leaving venturi 70 is thus humidified for application to cannula 48. Use of venturi 70 in this manner eliminates the need of additional or more complicated valving means and protects the humidifier 62 from higher pressures it might otherwise receive.

With respect to the embodiment of Fig. 6, a true signal on line L3 causes not only the valve 26 to allow the passage of a pulse of a first gas therethrough, but also causes the valve 126 to be actuated to connect the source 120 of the second gas to the cannula 48. In this respect, the true signal on lines L3 and L3' cause valve 126 to be actuated so that port 126a is communicable with port 126b. A pulse of second gas is thereby supplied through lines 144 and 46 to the cannula 48.

The duration of the pulse of the second gas is determined in the same manner as the duration of the pulse of the first gas. The amplitude of the pulse of

the second gas is determined in much the same manner as the amplitude of the first gas, being dependent on the inherent resistance VR of the valve 126 and the pressure of the source 120. It should be understood that, if desired, the apparatus of Fig. 6 can operate in the spiked pulse mode by connecting a flowmeter between valve 126 and source 120.

The system of Fig. 6 provides the same protective features for the in vivo respiratory system as do any of the foregoing embodiments. Additionally, the second gas (such as an anesthetic), is supplied only when the first gas (such as oxygen) is also being supplied.

It has been described above how the controller 32 protects the in vivo respiratory system from overoxygenation should the in vivo respiratory sytem attempt an abnormally high number of inspirations. The following discussion illustrates how the controller 32 indicates that the in vivo respiratory system is failing to attempt a further inspiration within a maximum time interval.

As mentioned above, when an inspiration (negative pressure from the in vivo respiratory system) is sensed, both input terminals of NOR 82 are true. The resultant false output of NOR 82 is applied to input pin 2 of the timer 88, as well as to the base of transistor T2. Transistor T2, being a PNP type, conducts to discharge capacitor C8. The transition from a true to a false input ot pin 2 of timer 88 results in a true output on pin 3 of timer 88. The true output signal from pin 3 is applied to alarm circuit 100 so that the piezo element 96 therein remains inactive. Likewise, the true output signal from pin 3 is applied to both input terminals of NOR 86, resulting in a false output signal from NOR 86 at point 104. The false output from NOR 86 does not

trigger the LED 94 nor does it affect input terminal 80b of NOR 80.

When negative pressure is not sensed in the in vivo respiratory system, the output signal from NAND 72 is false. This false output signal, applied to both input terminals of NOR 82, results in a true output from NOR 82. The true output signal from NOR 82 is applied to the base of transistor T2, causing T2 to stop conducting. Pin 2 of timer 88 is prevented from triggering. As transistor T2 stops conducting, capacitor C8 charges up. When capacitor C8 charges up to the threshold level of pin 6 of timer 88, the output pin 3 of timer 88 goes false. A false output on pin 3 of timer 88 energizes the alarm circuit 100 so that an audible signal is produced by the piezo element 96 in a conventional manner. False signals applied to both input terminals of NOR 86 result in a true output signal at point 104. The true signal at point 104 energizes the LED 94 to indicate an apneic event.

The true signal at point 104 is also applied to the input terminal 80b of NOR 80. Since the output signal of NAND 72 applied to terminal 80a of NOR 80 is false, the output terminal of NOR 80 goes false. The transition from true to false at pin 6 of the timer 90 causes a pulse of gas to be supplied to the in vivo respiratory system in the manner described above. If no further attempted inspiration is sensed, sequential pulses of gas are supplied in the same manner.

From the foregoing it should be apparent that a timer 90 provides a maximum time interval, and that the in vivo respiratory system must attempt a further inspiration before the expiration of the maximum time interval. If the maximum time interval is exceeded by the lapse of time from a next preceeding application of a pulse of gas to a sensing of negative pressure, the timer 88 functions to activate both the audible alarm

of circuit 100 and the visible alarm of LED 94, as well as to trigger timer 90 so that a further pulse of gas is provided. The duration of the maximum time interval depends on the particular valve of the resistance Ra, Rb, Rc,...manually chosen by the switch 100. This resistance valve determining the rate at which capacitor C8 charges, which in turn determines the time at which the threshold voltage applied to pin 6 of the timer 88 is sufficiently high for the output state of pin 3 thereof to change.

The apparatus of the embodiment of Fig. 8A somewhat resembles the apparatus of the embodiment of Fig. 1C, but the apparatus of Fig. 8 has its sensor 28C' adapted for compatibility with an apnea detection and occlusion prevention (ADOP) circuit 200. The ADOP circuit 200 is a predominately fluidically operated circuit comprising a first fluidic timing circuit 202; a fluidic NOR gate 204; a second fluidic timing circuit 206; and, valve means 208.

The sensor circuit 28C' resembles the circuit 28 of Fig. 5 with two exceptions: (1) point 104 intermediate LED 94 and NOR 86 is not tied to the input terminal 80b of NOR 80, and (2) the output port 30c of fluidic amplifier 30 is connected by a line 210 to a point 212 in the first timing circuit 202.

Point 212 of the timing circuit 202 is connected by parallel lines 214 and 216 to a point 218. Intermediate points 218 and 212, line 214 has a fluid resistance 220 thereon while line 216 has an exhaust means, such as a mushroom valve 222, thereon. The mushroom exhaust valve 222 is oriented so that a fluid signal from point 212 is transmitted to point 218, but a fluid signal from point 212 to the valve 222 prevents 218 from rapidly exhausting to atmosphere.

Point 212 of the timing circuit 202 is connected by line 224 to a first capacitance, such as variable volume elastomeric capacitance 226. Capacitance 226 is adapted to function in the manner of a comparable capacitance similarly depicted in U.S. patent application Serial No. 210,653, filed 26 November 1980 (incorporated herein by reference) but has a considerably longer potential volume for reasons seen hereinafter. Point 224 of circuit 202 is connected by line 228 of the NOR gate 204.

NOR gate 204 comprises a power stream input port 204a connected to a source 230; a control port 204b; a first output port 204c; and, a second output port 204d. Line 228 is connected to the control port 204b. A line 232 is connected from output port 204d to the second fluidic timing circuit 206. NOR gate 204 is of a type that, unless a signal is applied at port 204b to deflect output to port 204d, provides output at port 204c.

Output port 204d of NOR gate 204 is connected by lines 232 and 234 to a positive pressure input terminal of a conventional pressure-to-electric (P/E) switch 236. Switch 236 is connected by an electrical line L9 to indicator means 242 which includes, for example, one or more of the following: audible alarm means, visual alarm means, and counter means.

The second fluidic timing circuit 206 is essentially a fluidic one-shot comprising a first output port 206a vented to atmosphere; a second output port 206b connected via line 240 to the valve 208; a first input port 206c connected to a source 230; a second input port 206d; and, a third input port 206e. Input port 206d is connected by line 232 to output port 204d of the NOR 204. The fluidic timing circuit 206 further comprises a substantially closed-loop fluidic path 244 which has a first end thereof communicating

with port 206d and a second end thereof communicating with port 206e. The fluidic path 244 has thereon one or more timing means, such as a fluid restrictive device 246 and/or a capacitance device 248. As shown in the embodiment of Fig. 8, the restrictive device 246 is a variable resistor and the capacitance 248 is a variable capacitance, such as an elastomeric balloon. The restrictive device 246 and capacitance 248 can be interchanged with similar restrictive devices or capacitances having different values and capacitances as desired.

As mentioned above, output port 206b of the fluidic timing circuit 206 is connected via line 240 to the valve means 208. Valve 208 as shown is a two-way, two position solenoid spool valve, such as an ALCON Series A Model 7986 valve. Although any suitable conventional valve may be utilized. Valve 208 has two port 208a and 208b in its bore. Valve 208 is connected so that a positive pressure on line 240 moves the valve 208 into the position shown in Fig. 8A wherein port 208a thereof is connected to port 208b.

Port 208b of valve 208 is connected by line 250 to a point 252 on line. A fluidic resistor 254 on line 250 insures that the path of least resistance from the cannula 48 is through the line 46 and through the valve 26 rather than through line 250.

Port 208a of valve 208 is connected by a line 256 to a capacitance 258, which in turn is connected by line 260 to a flowmeter 262. Flowmeter 262 is connected by line 264 to a pressure regulator 266. Pressure regulator 266 is connected to a source 268.

The embodiment of Fig. 8B basically resembles the embodiment of Fig. 8A but does not employ the second fluidic timing circuit 206 and the valve means 208. Instead, the positive pressure port of the P/E switch 236 is directly connected to the output port

204d of NOR 204. The electrical output of the P/E switch 236 is connected a electrical line L10 through an electrical stimulation controller 274 to a conventional electromyographic electrode 270. Electrode 270 is positioned under the chin of a patient in close proximity to a hypoglossal nerve (the twelfth cranial nerve).

The operation of the apparatus of the embodiment of Fig. 8C basically resembles the operation of the embodiment of Fig. 1C. However, with the controller 32' of Fig. 8C, when the timer 88 of controller 32' determines that the in vivo respiratory system has not attempted a further inspiration before the expiration of a first maximum time interval, timer 90 is not triggered to provide a further pulse of gas. Moreover, although a short apnea event corresponding to the first maximum time interval has already occurred and been indicted by LED 94 and alarm circuit 100, the embodiment of Fig. 8C further functions to (1) determine when the in vivo respiratory system has failed to attempt a further inspiration before the inspiration of a second maximum time interval (the second maximum time interval being greater than the first maximum time interval and indicative of a long apnea event), and (2) to provide a high pressure pulse of gas to the in vivo respiratory system in an attempt to dislodge any occlusion or obstruction in the upper airway passages of the in vivo respiratory system.

In the above regard, when output indicative of non-negative pressure in the in vivo respiratory system occurs at port 30e of amplifier 30, the output is applied to the first fluidic timing circuit 202. The fluidic output signal travels around line 216 of circuit 202, closing the mushroom valve 222. From thence the signal is applied to the variable capacitance 226 on line 224. The fluid signal is

continuosly applied to the variable capacitance device 226 so long as output occurs at port 30e of amplifier 30.

In normal breathing the output of amplifier 30 will switch to port 30d long before the variable capacitance device 226 is filled to its maximum capacity. In this regard, it is recalled that amplifier 30 switches its output from port 30e to port 30d when an inspiration is sensed. In this case, the patient is breathing satisfactorily and there is no apneic event.

In abnormal breathing, however, when the patient fails to inspire, amplifier 30 continues to generate a fluid signal on output port 30e. Accordingly, the variable capacitance device 226 continues to expand until it is inflated to its maximum capacity. When the variable capacitance device 226 is inflated to a pressure which expands it to its maximum capacity, the fluid pressure builds on line 228 and causes the power stream entering port 204a of NOR gate 204 to switch from output port 204c to output port 204d. In this manner, the NOR gate 204 creates a fluid signal on line 232. The fluid signal on lines 232 and 234 are connected to the pressure/electric switch 236 which converts the fluid signal on line 234 to an electric signal on line L9. The electric signal can perform various diagnostic operations, such as activate an electrocardiogram (ECG) monitor, an alarm, or a counter.

Various sizes and types of elastomeric balloons or other appropriate devices may be chosen for the variable capacitance device 226. Factors to be considered in making the choice of which device to use include the elastomeric tension exerted by the device and the maximum fluid-storing capacity of the device. For example, if it were desired that the apneic event

circuit 200 indicate that the patient has not inspired within a 60 second-second maximum time interval, the device 226 should be selected so that it can accommodate the volume of fluid generated by amplifier 30 for that 60 second period without triggering a switch in NOR gate 204. Of course, should the patient inspire before the variable capacitance device 226 reaches its maximum pressurized capacity, the device 226 acting in conjunction with the mushroom valve 222 is quickly deflated in the manner described above.

It should be evident from Fig. 8A that, absent a fluid signal on line 232, the power stream entering port 206c of the circuit 206 is vented to atmosphere through output port 206a. However, when the fluid signal is applied on line 206d, the power stream entering at port 206c is deflected to the output port 206b for a period of time in the manner hereinafter described.

Upon application of the fluid signal on line 232 to the port 206d of the second circuit 206, the power stream entering port 206c is deflected from the output port 206a to the output port 206b, thereby creating a fluid signal on line 240 which is applied to the valve means 208. The fluid signal on line 232 is also applied to the fluidic path 244 which has thereon timing means (such as the resistance 246 and the capacitance device 248). The timing means delays the passage of the first fluid signal around the closed loop fluidic path 244 for a pre-determined time. That is, an appropriate value is chosen for the resistance of the variable resistor 246 and a capacitance device 248 of appropriate maximum capacity is chosen so that the first fluid signal travelling around the closed loop fluidic circuit 244 will be delayed for a pre-determined time before the signal reaches the port 206e of the fluidic circuit 206. When the fluid signal

travelling around the closed loop fluidic path 244 reaches the port 206e, the fluidic pressure on each side of the power stream entering at port 206c is equalized so that the power stream is no longer deflected out the port 206b but instead is again vented to atmosphere through the port 206a.

The valve 208 receives a supply of gas ultimately from source 268 but can transmit the gas only when a fluidic signal is applied on line 240 in the manner described above. When a fluidic signal is applied on line 240, the valve 208 is operated to connect port 208a thereof to port 208b for a time period whose duration is determined by the duration of the signal on line 240. As seen above, this duration of the signal on line 240 is determined by the selected values associated with the resistance and capacitance of the delay loop 244.

Valve 208 functions to provide a high pressure pulse of gas through line 250 to the single hose cannula 48 in an effort to dislodge an upper airway obstruction or occlusion which may have caused the long apnea event. In some instance the pressure supplied by the pulse should be as high as 50 pounds per square inch. The amplitude of the pulse is controllable through the various devices (regulator 266, capacitance 258, flowmeter 262) shown connected intermediate valve 208 and source 268.

It should be understood that various methods can be used to operate the apparatus of Fig. 8A. For example, in one mode of operation a high pressure pulse of limited duration is applied. In another embodiment the fluid circuit 206 can be adapted so that a high pressure pulse trails off to a continuous flow of lesser pressure. It can yet be envisioned that a series of high pressure pulses can be applied in a programmable manner.

The embodiment of Fig. 8B functions much in the manner of Fig. 8A but, rather than supply a high pressure pulse of gas through a valve means, uses the P/E switch 236 to generate an electrical signal on line L10 for application to the electrode 270. Electrode 270, positioned under the chin in close proximity to a nerve controlling a muscle or the like, such as the hypoglossal nerve for the tongue, provides stimulus for the muscle to dislodge itself from the upper airway so that the movement of the muscle and associated organs can again be in coordination with the diaphragm of the in vivo respiratory system.

Fig. 8C illustrates a further embodiment of the invention which accomplishes objectives similar to that of the embodiment of Fig. 8A. The apparatus of Fig. 8C resembles the apparatus of Fig. 6. The controller 32' of Fig. 8C, however, does not have its point 104 connected to the input terminal 80b of NOR 80. Rather, point 104 is connected by line L7 to a two-position two port solenoid spool valve 272. Valve 272 of Fig. 8C is connected to a source 268 in much the same manner as valve 208 of Fig. 8A is connected to source 268.

In the operation of the embodiment of Fig. 8C, whenever controller 32' determines that an apnea event [having a duration corresponding to a predetermined yet variably selectable maximum time interval established by the position of switch 100] occurs, a high pressure pulse of gas is supplied through the operation of valve 272 in a manner easily understood from the foregoing other embodiments.

It should be understood that sensing means 28C of the embodiment of Fig. 1C may be used with any of the embodiments disclosed herein. Also, each of the disclosed embodiments may be appropriately modified as discussed above to operate in either a spiked pulse or

a square pulse mode. Further, it should be understood by those skilled in the art that the solenoid operated spool valves disclosed herein may be replaced with latching solenoid valves, such as the Pneutronics Series 11 valve.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. An apparatus for sensing negative pressure in an in vivo respiratory system and for supplying gas to said in vivo respiratory system, said apparatus comprising:

valve means having a first port selectively communicable with a second port and a third port;

a line connecting said in vivo respiratory system to said first port of said valve means, said line adapted both to transmit to said valve means negative pressure indicative of an inspiration in said in vivo respiratory system and to transmit gas to said in vivo respiratory system;

a source of gas communicating with said second port of said valve means;

means for sensing negative pressure in said in vivo respiratory system, said sensing means communicating with said third port of said valve means; and,

means for controlling said valve means, said control means being responsive to said sensing means for selectively connecting said first port of said valve means to said second port thereof when negative pressure is sensed and for maintaining said connection for at least a portion of the time duration of said negative pressure in said in vivo respirtory system so that gas may be supplied to said in vivo respiratory system, said control means also being adapted to reconnect said first port of said valve means to said third port thereof after the application of gas to said in vivo respirating system.

2. An apparatus for sensing negative pressure in an in vivo respiratory system and for supplying humidified gas to said in vivo respiratory system, said apparatus comprising:

valve means having a first port selectively communicable with a third port and a second port communicable with a fourth port;

a line connecting said in vivo respiratory system to said first port of said valve means, said line adapted to both transmit to said valve means negative pressure indicative of an inspiration in said in vivo respiratory system and to transmit humidified gas to said in vivo respiratory system;

a source of gas communicating with said second port of said valve means;

means for sensing negative pressure in said in vivo respiratory system, said sensing means communicating with said third port of said valve means;

humidifying means, said humidifying means having an input port connected to said fourth port of said valve means and an output port connected to said line connecting said in vivo respiratory system to said first port of said valve means; and,

means for controlling said valve means, said control means being responsive to said sensing means for selectively connecting said fourth port of said valve means to said second port thereof when negative pressure is sensed and for maintaining said connection for at least a portion of the time duration of said negative pressure in said in vivo respiratory system so that humidified gas may be supplied to said in vivo respiratory system, said control means also being adapted to reconnect said first port of said valve means to said third port thereof after the appliction of humidified gas to said in vivo respiratory system.

3. A method of supplying gas to an in vivo respiratory system comprising the steps of:

predetermining a required minimum delay interval between successive applications of said gas to said in vivo respiratory system;

connecting said in vivo respiratory system to sensing means;

using said sensing means to sense negative pressure at the beginning of inspiration in said in vivo respiratory system;

determining if said sensing of negative pressure in said in vivo respiratory system occurs within said delay interval with respect to a next preceeding application of said gas to said in vivo respiratory system;

connecting said in vivo respiratory system to a supply of gas for a pre-established time duration only if said sensing of negative pressure in said in vivo respiratory system does not occur within said delay interval, said connection facilitating an application of said gas to said in vivo respiratory system; and,

reconnecting said in vivo respiratory system to said sensing means after an application of said gas to said in vivo respiratory system.

4. A method of supplying gas to an in vivo respiratory system comprising the steps of:

predetermining a required minimum delay interval between successive applications of said gas to said in vivo respiratory system;

using a single hose cannula to connect said in vivo respiratory system to a valve means, said valve means being operable to make said in vivo respiratory

system selectively communicable with a sensing means and with a supply of said gas;

using said sensing means to sense negative pressure at the beginning of inspiration in said in vivo respiratory system;

determining if said sensing of negative pressure in said in vivo respiratory system occurs within said delay interval with respect to a next preceding application of said gas to said in vivo respiratory system;

operating said valve means to communicate said in vivo respiratory system with said supply of gas for a pre-established time duration only if said sensing of negative pressure in said in vivo respiratory system does not occur within said delay interval, said communication facilitating an application of said gas to said in vivo respiratory system; and,

operating said valve means to recommunicate said in vivo respiratory system with said sensing means after an application of said gas to said in vivo respiratory system.

5. An apparatus for sensing negative pressure indicative of inspiration in an in vivo respiratory system and for supplying gas to said in vivo respiratory system, said apparatus comprising:

means for sensing negative pressure in said in vivo system;

valve means operable for selectively supplying said gas to said in vivo system;

control means responsive to said sensing means for operating said valve means so that said gas

is supplied to said in vivo system for at least a portion of the time duration of an occurrence of sensed negative pressure;

first timer means connected to said sensing means for determining when a first predetermined time interval has elapsed since the last occurrence of negative pressure in said in vivo system; and,

means responsive to said first timer means for simulating a nerve associated with an in vivo organ so that an upper airway passage in said in vivo respiratory system is not occluded.

6. An apparatus for sensing negative pressure indicative of an inspiration in an in vivo respiratory system and for supplying gas to said in vivo respiratory system, said apparatus comprising:

means for sensing negative pressure in said in vivo system;

valve means operable for selectively supplying said gas to said in vivo system;

control means responsive to said sensing means for operating said valve means so that said gas is supplied to said in vivo system for at least a portion of the time duration of an occurrence of sensed negative pressure;

first timer means connected to said sensing means for determing when a first predetermined time interval has elapsed since the last occurence of negative pressure in said in vivo system; and,

means responsive to said first timer means for dislodging an obstruction in an upper airway passage of said in vivo respiratory system by supplying a positive pressure pulse of gas to said in vivo system.

7. A method for supplying gas to an in vivo respiratory system and for monitoring the condition of said in vivo respiratory system, said method comprising the steps of:

sensing negative pressure in said in vivo respiratory system;

using valve means to selectively supply gas to said in vivo system;

controlling the operation of said valve means so that gas is supplied to said in vivo system for at least a portion of the time duration of an occurrence of sensed negative pressure;

determining when a first pre-determined time interval has elapsed since the last occurrence of negative pressure in said in vivo system; and,

stimulating a nerve associated with an in vivo organ upon the detection of the elapse of said first pre-determined time interval so that an upper airway passage in said in vivo respiratory system is not occluded.

8. A methof for supply gas to an in vivo respiratory system and for monitoring the condition of said in vivo respiratory system, said method comprising the steps of:

sensing occurrences of negative pressure insaid in vivo respiratory system;

using valve means to selectively supply gas to said in vivo system;

controlling the operation of said valve means so that gas is supplied to said in vivo system for at least a portion of the time duration of an occurrence of sensed negative pressure;

detecting when a first pre-determined time interval has elapsed since the last occurrence of negative pressure in said in vivo system; and,

dislodging an obstruction in an upper airway passage of said in vivo respiratory system by supplying a positive pressure pulse of gas to said upper airway passage of said in vivo system.

9. An apparatus for sensing pressure direction in an in vivo respiratory system and for supplying gas to said in vivo respiratory system, said apparatus comrpising:

sensing means for sensing pressure direction in said in vivo respiratory system, said sensing means comprising:

a biased fluidic amplifier, said amplifier comprising a control port, a first output port, and a secnd output port, said amplifier being biased so that, unless a negative pressure signal is applied at a said control port, a fluidic output signal normally occurs at said first output port;

fluid pressure-to-electric conversin means, said conversion means having a positive pressure input port thereof fluidically connected to said second output port of said biased fluidic amplifier for receiving a fluidic output signal form said biased amplifer and for converting said fluidic signal to an electrical signal;

a source of gas to be supplied to said in vivo respiratory system;

valve means responsive to said electrical signal of said sensing means for selectively applying gas to said in vivo respiratory system;

means for fluidically communicating said source of gas to said valve means; and,

means for fluidically communicating said valve means to said in vivo respiratory system.

Fig 1A.

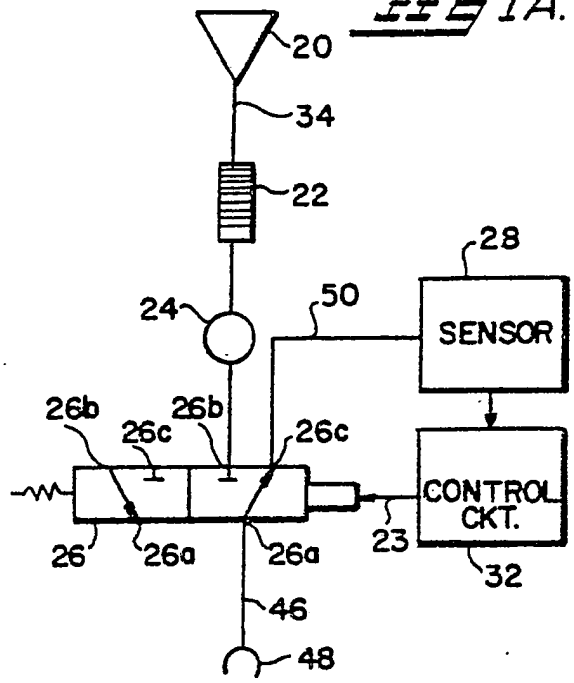


Fig 1B.

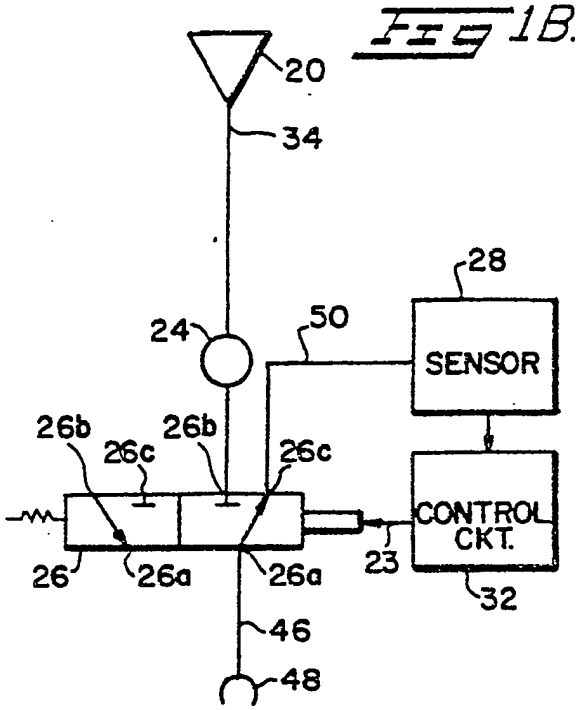


Fig 1C.

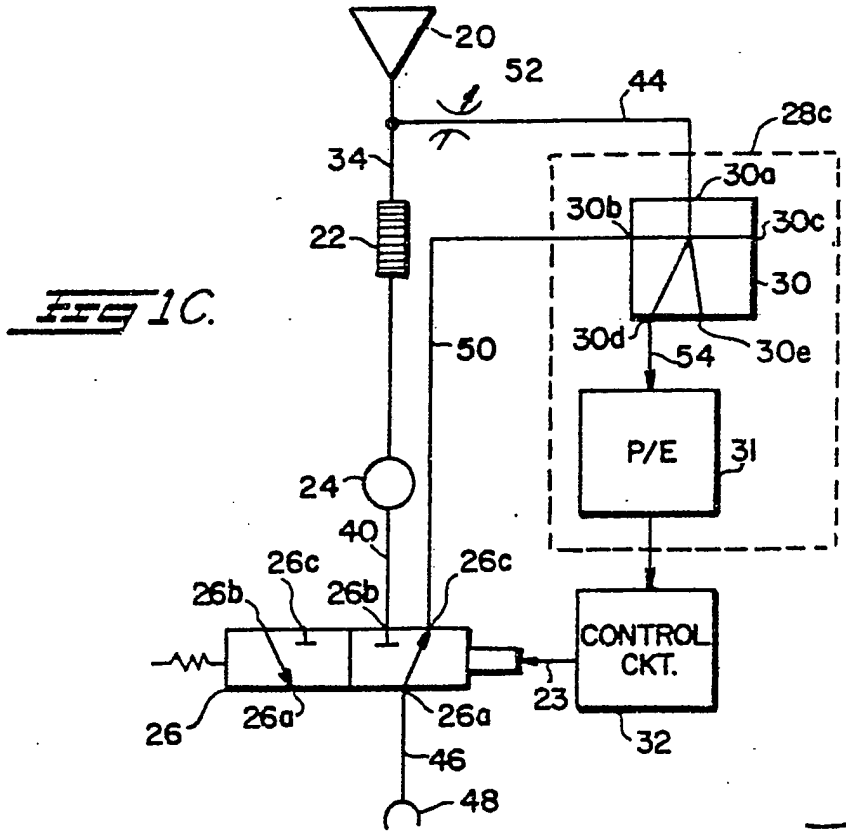


Fig 7A.

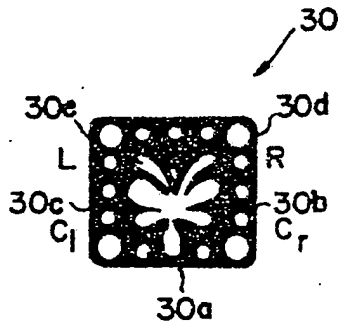
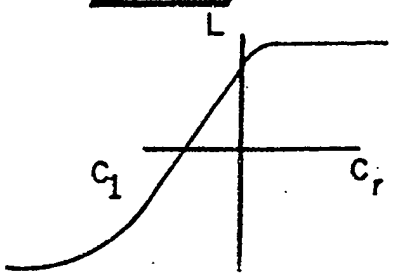


Fig 7B.



SUBSTITUTE SHEET

Fig 2.

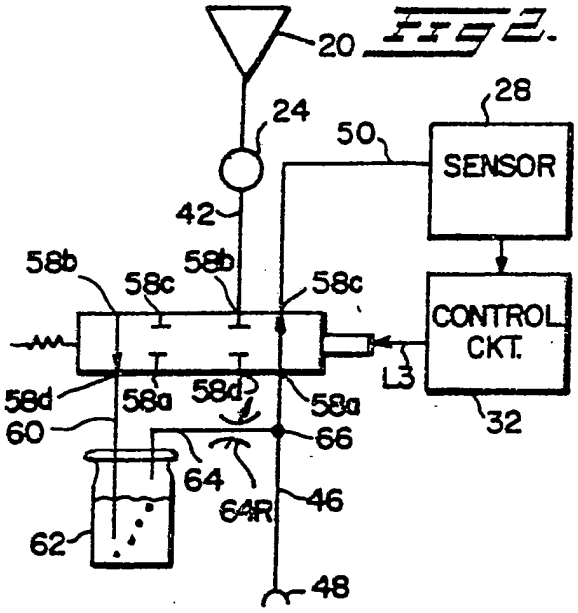


Fig 3.

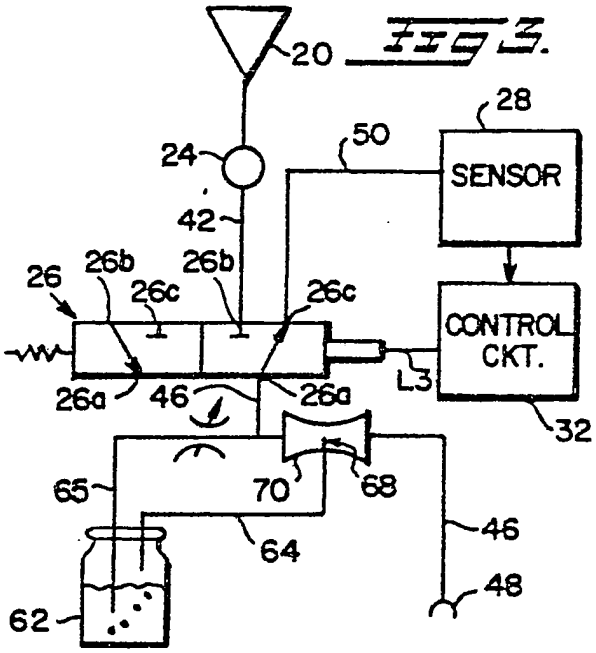


Fig 6.

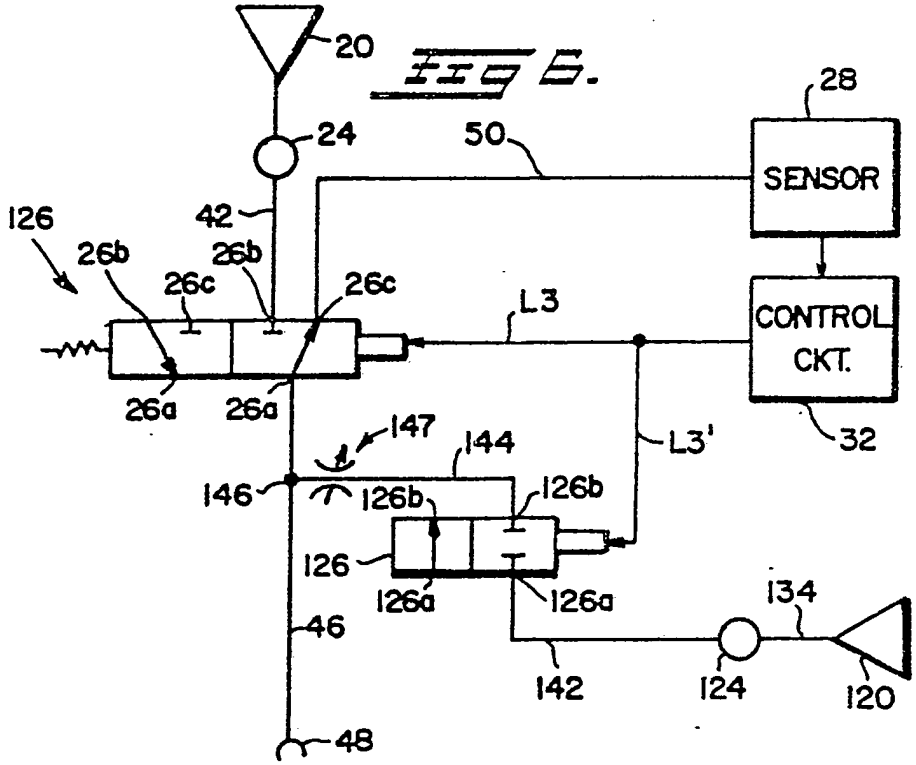


Fig 4A.

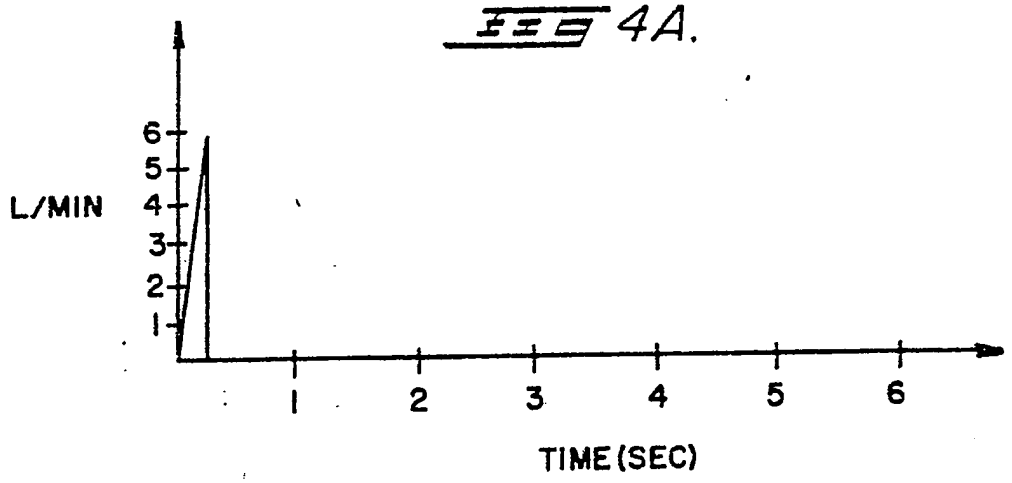
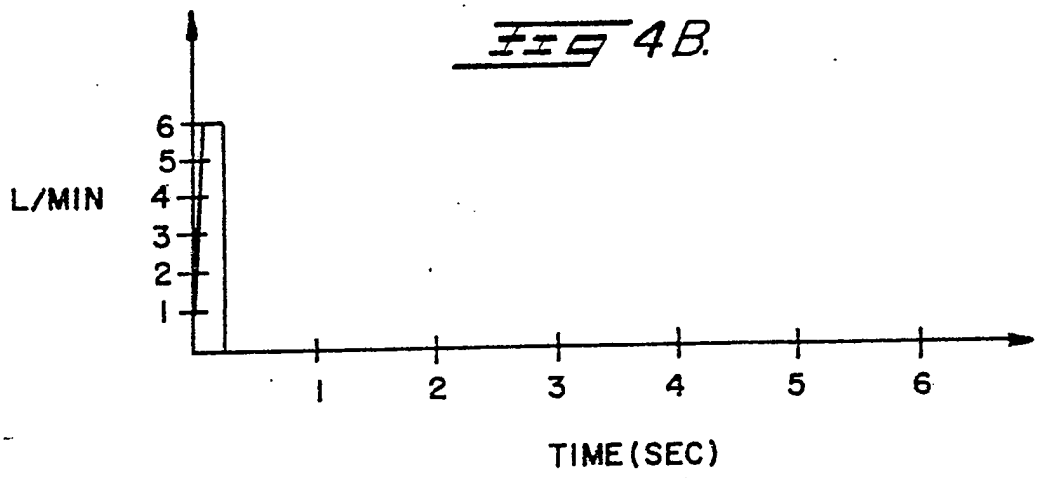


Fig 4B.



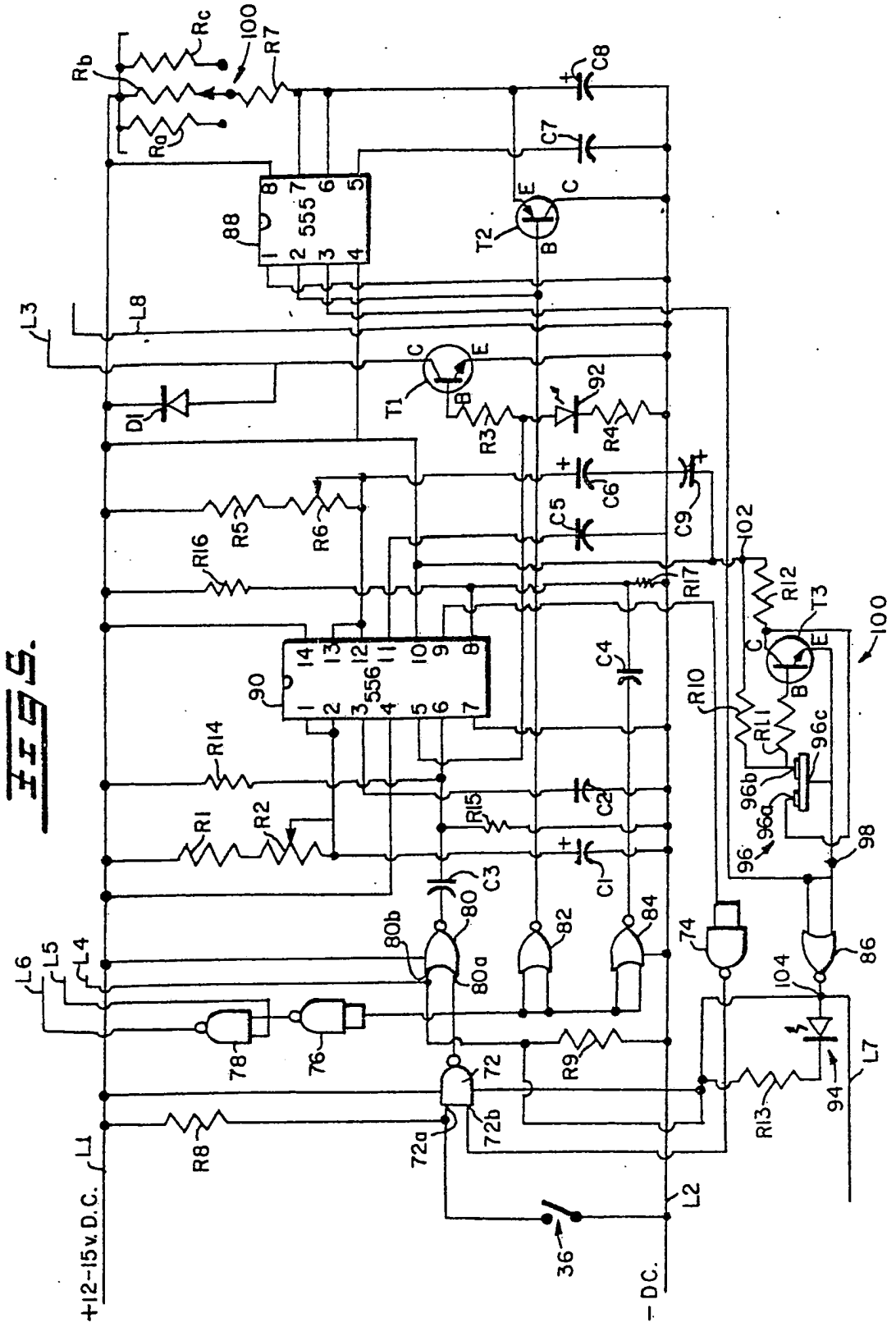


FIG 5.

FIG 8A.

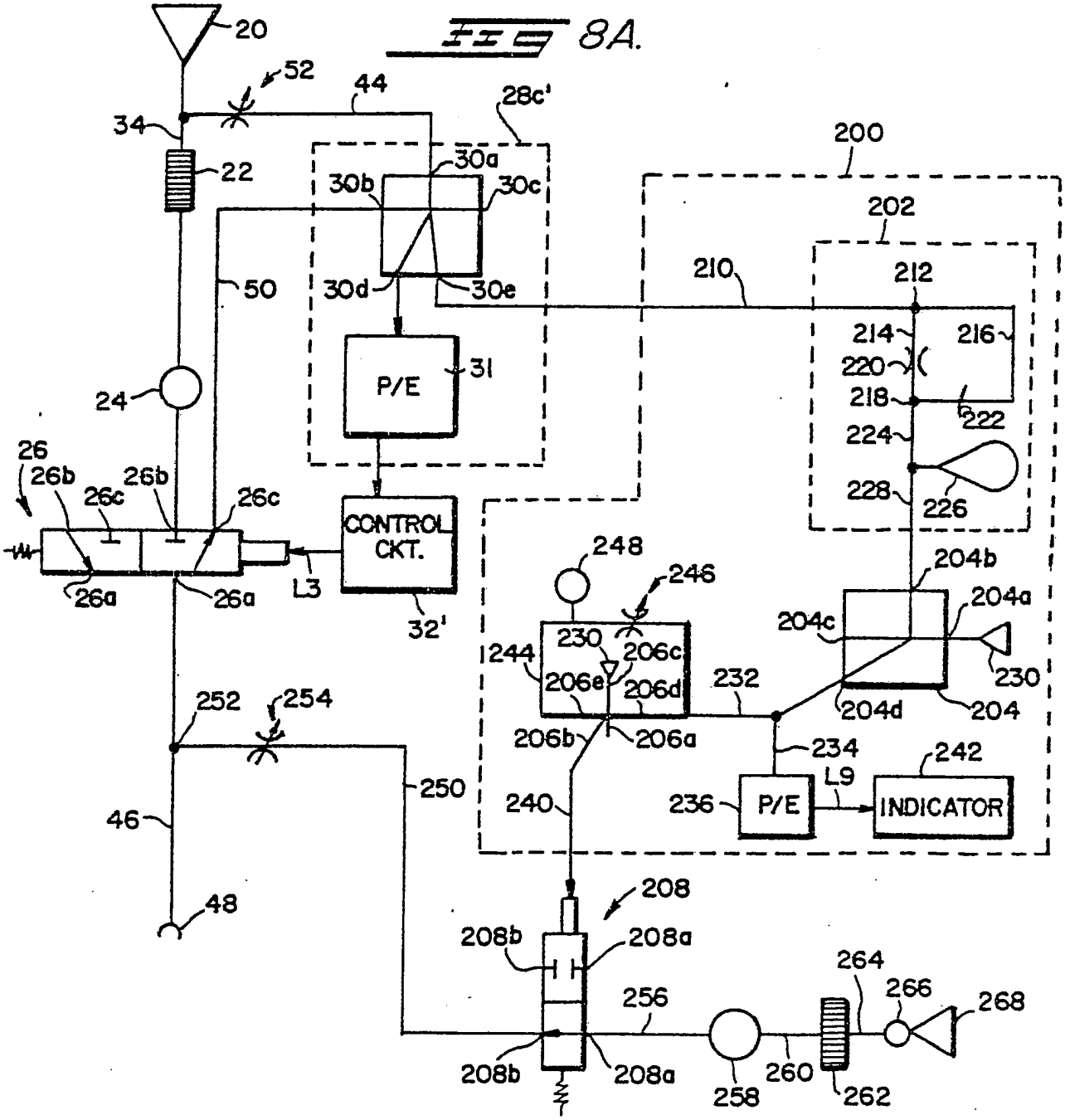


FIG 8B.

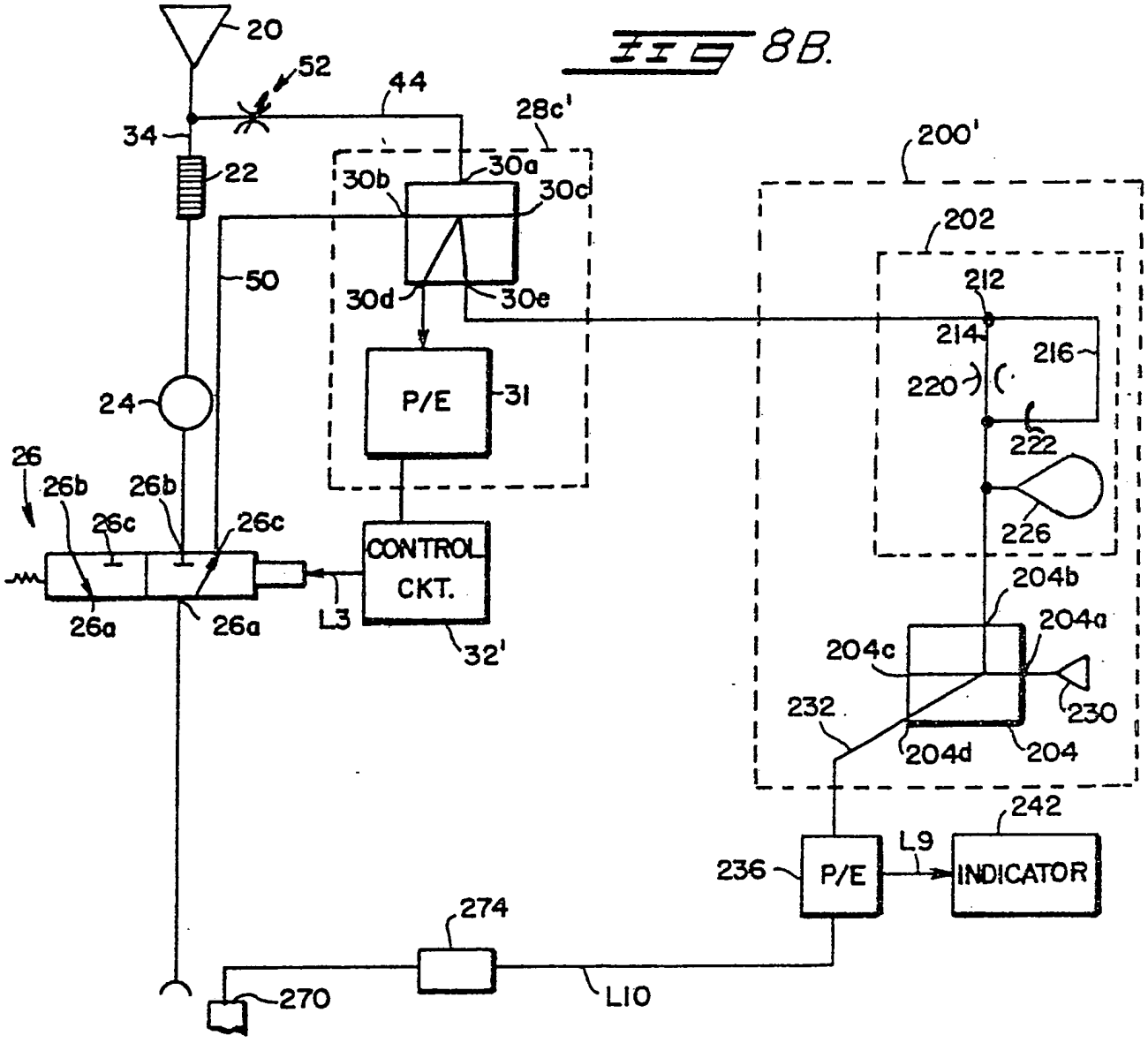
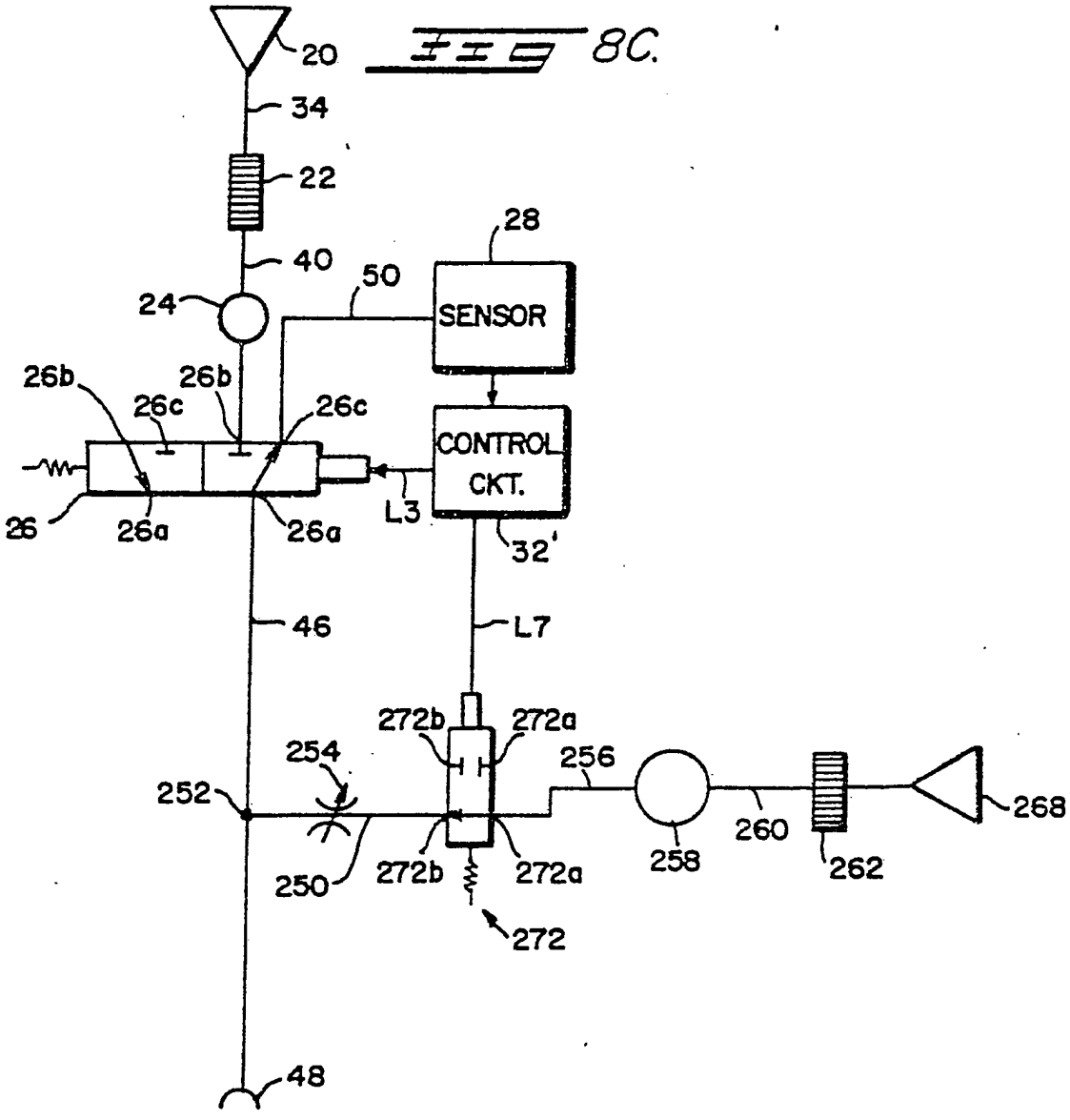


FIG 8C.



INTERNATIONAL SEARCH REPORT

International Application No PCT/US83/01890

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC-A61M-15/00
NC-128/204.23

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols
U.S.	128/28,203.12,204.21,204.22,204.23,204.24,204.25, 204.26,204.28,205.11,205.14,205.15,205.16,205.19, 205.24,205.25,419G,725,725,202.22,205.17,200.14

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [5]

CL. System Cont. 137/834,841

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No. [18]
A	US, A, 3,357,428 12 December 1967 CARLSON	1,2
A	US, A, 4,289,126 15 September 1981 SEIREG et al	1,2
A	US, A, 3,097,638 16 July 1963 STREIMER	1,2
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A	US, A, 4,206,754 10 June 1980 COX et al	1,2
A	US, A, 4,215,681 05 August 1980 ZALKIN et al	1,2
A	US, A, 3,863,630 04 February 1975 CAWALLO	1,2
A	US,A, 4,186,737 05 February 1980 VALENTA et al	1,2
A	US, A, 3,820,539 28 June 1974 OLLIVIER	1,2
A	US, A, 3,611,178 05 October 1971	1,2
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A,P	US, A, 4,393,869 19 July 1983 BOYARSKY et al	1,2,9
X,Y	US, A, 4,121,579 24 October 1978 BIRD	3,4,6,8
X,Y	US, A, 3,976,064 24 August 1976 WOOD et al	3,4,6,8
E,P	G.B. A, 2,101,895 26 January 1983 EDWARD et al	3,4,6,8

* Special categories of cited documents: [15]

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IV. CERTIFICATION

Date of the Actual Completion of the International Search [2]	Date of Mailing of this International Search Report [2]
FEB 8 1984	09FEB 1984
International Searching Authority [1]	**Signature of Authorized Officer [20]**
ISA/US	Henry J. Sullivan

Form PCT/ISA/210 (second sheet) (October 1981)

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No [18]
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A	US, A, 3,942,513 09 March 1976 FRANK	5,7
A	US, A, 4,155,356 22 May 1979 VENEGAS	3-8
A	US, A, 4,226,233 07 October 1980 KRITZER	3-8
A	US, A, 4,062,358 13 December 1977 KRITZER	3-8
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A	"Reversal of Obstructive Sleep Apnoes by Continuous Positive Airway Pressure Applied through the Nares", THELANCET pp-862-865 18 April 1981 SALLIVAN et al	3-8
A	US, A, 4,054,133 10 October 1977 MYERS	9
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A	US, A, 3,494,357 10 February 1970 KIMBALL	9

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(71) Applicant: EDENTEC [US/US]; 10252 Valley View Road, Eden Prairie, MN 55344 (US).

(71)(72) Applicants and Inventors: SHANNON, John, L., Jr. [US/US]; 2780 White Oak Circle, Orono, MN 55424 (US). BOWMAN, Bruce, R. [US/US]; 9296 Amsden Way, Eden Prairie, MN 55344 (US).

(74) Agent: ROONEY, John, L.; 3433 Broadway St. N.E., Suite 401, Minneapolis, MN 55413 (US).

(81) Designated States: AT (European patent), AU, BE (European patent), CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FI, FR (European patent), GB (European patent), GR (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent).

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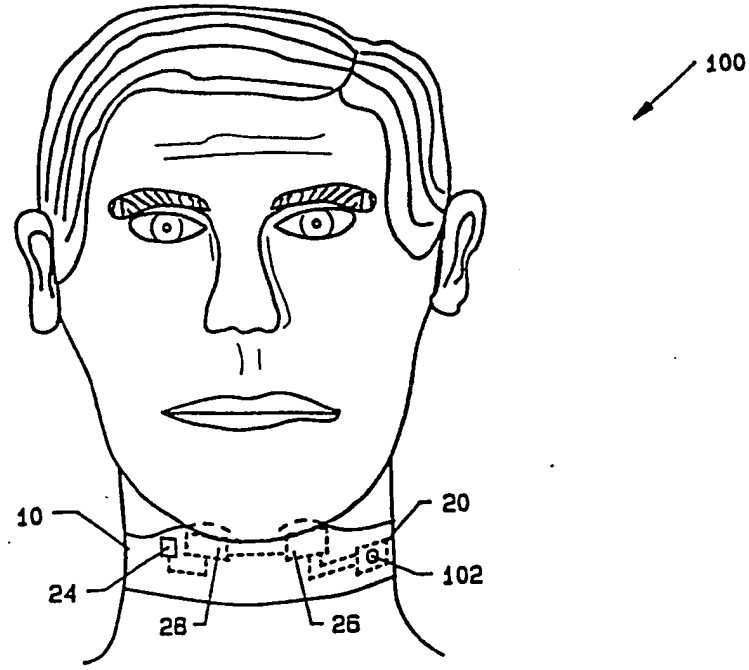
(54) Title: OBSTRUCTIVE SLEEP APNEA COLLAR



(57) Abstract

A system for the treatment of obstructive sleep apnea packaged in a collar (10) which can be worn by a patient without any special preparation. The collar (10) has an adjustable attachment means, such as hook (14) and latch (16), to accommodate variations in neck size. The coliar (10) is properly oriented using variations in physical shape and/or color. An optional feedback system permits the patient to readily verify proper orientation. The collar (10) contains at least one sensor (24) to monitor functioning of the respiratory system of the patient. Suitable parameters to be sensed include breath or snoring sounds, breath temperature, air flow, blood gases via either direct or indirect means, motion of the chest, circumference of the chest, expansion of the chest, resistance of the airway via either direct or indirect means, and expansion of the neck. Preferably, the sensor (24) is properly positioned directly with attachment of the collar.

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OBSTRUCTIVE SLEEP APNEA COLLAR

CROSS REFERENCE TO CO-PENDING APPLICATIONS

None.

BACKGROUND OF THE INVENTION

1. Field of the Invention - The present invention relates generally to medical devices, and more particularly, relates to transcutaneous electrical stimulation treatment of obstructive sleep apnea.

2. Description of the Prior Art - Sleep apnea is a medical condition which effects a large segment of the population. It exists in several forms. Perhaps the most dangerous, called central apnea, is associated with a lack of central drive to breath or with a disruption of the neural pathways from the brain to the diaphragm muscles. Research has been progressing for some time with one mode of treatment being electrical stimulation of the phrenetic nerve, thereby controlling function of the diaphragm. William W. L. Glenn describes the nature of this research in "Diaphragm Pacing: Present Status" in Pace, Volume 1, pages 357 - 370, July - September 1978.

A second form of sleep apnea, and of most concern to the present invention, is that which obstructs the upper air passageways. This condition has numerous deleterious results including disturbance of the patient and sleep partner and loss of effectiveness of the sleep process resulting in excessive patient fatigue. Long term effects include hypertension and cardiac problems.

The simplest forms of treatment for upper air passage obstructive sleep apnea involve mechanical constraints. U.S. Patent No. 4,304.227 issued to Samelson describes such a device. Various surgical techniques are also employed including tracheostomy.

Perhaps the most common technique is through the use of systems which detect the obstructive condition and alert the patient to the problem in some fashion. Examples of this type of system include: U.S. Patent No. 2,999,232 issued to Wilson; U.S. Patent No. 3,032,029 issued to Cunningham; U.S. Patent No. 3,480,010 issued to Crossley; U.S. Patent No. 3,593,703 issued to Gunn et al.; U.S. Patent No. 3,696,377 issued to Wall; U.S. Patent No. 3,998.209 issued to Macvaugh; U.S. Patent No. 4,220,142 issued to Rosen et al.; and U.S. Patent No. 4,593,686 issued to Lloyd et al. These devices employ a variety of techniques, but each tends to be based upon detection of the condition and producing an alarm. Unfortunately, the alarm may rouse the patient to the extent that patient's sleep is disturbed, thereby exacerbating the very problem caused by the apnea episode.

Recently, research has been conducted which shows that the obstruction within the upper air passageway may be cleared with electrical stimulation. Two articles, herein incorporated by reference, describing this research may be found in American Review of Respiratory Disease Volume 140, 1989 at pages 1279 through 1289. The first article is "Effects of Electrical Stimulation of the Genioglossus on Upper

Airway Resistance in Anesthetized Dogs", by Hiroshi Miki et al. The second article is "Effects of Submental Electrical Stimulation during Sleep on Upper Airway Patency in Patients with Obstructive Sleep Apnea", also by Hiroshi Miki et al.

U.S. Patent No. 4,830,008 issued to Meer discusses an implantable system for treatment of obstructive sleep apnea using electrical stimulation. The implanted sensor(s) are used to sense inspiratory effort and stimulate the nerves of the upper airway in synchrony with the respiration cycle. Because upper airway stimulation may not be required for each inspiratory effort, Meer proposes an embodiment which also senses muscular activity in the upper airway to inhibit stimulation for certain respiratory cycles. However, it is not clear that the added complexity and morbidity of an implantable system are justified in the absence of evidence that stimulation only during the inspiratory effort is either necessary or sufficient.

SUMMARY OF THE INVENTION

The present invention overcomes the disadvantages of the prior art systems by providing an external device for the effective treatment of obstructive sleep apnea using a collar which may be easily and properly attached by the patient. The collar senses the onset of an apnea episode and automatically applies electrical signals which either stimulates the patient's muscles to clear the obstruction or stimulates a reflexive response of causing the patient's muscles to clear the obstruction. Because the device is worn externally, it does not require the expense and risk associated with an implant procedure. Because the electrical stimulation is supplied with little sensation, the effectiveness of sleep is preserved.

The collar is readily attachable using hook and latch or other suitable fasteners. Means located on the collar ensure proper placement of the sensor and stimulation electrodes. The positioning means can take the form of variations in shape or color of the collar. The collar is self contained; and therefore, promotes patient compliance through ease of use. It may be made in disposable form to ensure ease of manufacture.

A sensor located on or near the collar is used to determine the onset of an apnea episode. Proper functioning of the respiratory system may be monitored directly in the form of air flow, direct or indirect blood gas measurements (such as pulse oxygen saturation), or indirectly via breath or snoring

sounds, breath temperature, pressure sensors, thoracic impedance, strain gauges, or airway resistance. The output of the sensor is conditioned and interpreted, and used to determine whenever an apnea event is initiated. A stimulation signal is generated which is coupled to transcutaneous neuro muscular electrodes. These stimulation signals cause the genioglossus and related muscle groups to contract thereby clearing the upper air passageway.

BRIEF DESCRIPTION OF THE DRAWINGS

Other objects of the present invention and many of the attendant advantages of the present invention will be readily appreciated as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings, in which like reference numerals designate like parts throughout the figures thereof and wherein:

FIG. 1 is a plan view of an obstructive sleep apnea collar;

FIG. 2 is an obstructive sleep apnea collar showing an alternative positioning means;

FIG. 3 is an obstructive sleep apnea collar showing a second alternative positioning means;

FIG. 4 is a frontal view of a patient wearing an obstructive sleep apnea collar;

FIG. 5 is a side view of a patient wearing an obstructive sleep apnea collar;

FIG. 6 is an overall view of the electronic module of the obstructive sleep apnea collar; and,

FIG. 7 is a block diagram of the electronic circuit of the obstructive sleep apnea collar.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. 1 is a plan view of an obstructive sleep apnea collar 10 of the present invention. The main substrate 12 is of a flexible material suitable for wrapping about the patient's neck. Preferably main substrate 12 is of a porous woven material which permits the collar to "breathe". Main substrate 12 is fastened about the neck of the patient using convenient fasteners such as hook 14 and latch 16 (see also FIGS. 4 and 5). Preferably, hook 14 and latch 16 are sufficiently wide to permit adjustment to necks of varying sizes.

It is important that collar 10 be properly positioned when attached to the neck of the patient to ensure that the components located on main substrate 12 are properly positioned. In the preferred embodiment, this is accomplished with chin notch 18 which accommodates the chin of the patient. In this way, the patient can easily feel that collar 10 is properly positioned.

Sensor 24 is used to determine the onset of an apnea episode. In the preferred embodiment, this is a microphone or motion sensor which generates an electrical signal corresponding to the presence of breath or snoring sounds. Other sensors which may be used include an oximeter to measure the percentage of oxygen saturation of the blood, an airflow sensor, an airway resistance sensor, a strain gauge, or an impedance plethysmograph. Sensor 24 is fixedly mounted to main substrate 12 such that when collar 10 is

positioned using chin notch 18, sensor 24 is properly located for its monitoring function. Sensor 24 is electrically coupled to electronic module 20 using cable 30. Electronic module 20 contains the circuitry to process the sensor output and generate stimulation signals as required. Electronic module 20 is discussed in more detail below.

The electrical stimulation signals generated by electronic module 20 are coupled to electrode 26 and electrode 28 via cable 32 and cable 34, respectively. Electrodes 26 and 28 are similar to commercially available muscle stimulation electrodes. Each is fixed to main substrate 12 such that it will be properly located to stimulate the genioglossus and related muscle groups when collar 10 is in position.

FIG. 2 shows obstructive sleep apnea collar 11 employing a first alternative positioning means. Collar 11 has a color stripe 19 which the patient positions over his epiglottis. Collar 11 is constructed such that color stripe 19 is located the proper distance from hook 13 and latch 15.

FIG. 3 is a plan view of obstructive sleep apnea collar 21 using a second alternative positioning means. Collar 21 employs shoulder notches 27 and 29 which are spaced appropriately from hook 23 and latch 25. Unlike chin notch 18 (see also FIG. 1), shoulder notches 27 and 29 are located along the bottom surface of collar 21.

FIG. 4 is a frontal view of patient 100 with obstructive sleep apnea collar 10 properly positioned for treatment. All other components are as previously described.

FIG. 5 is a side view of patient 100 with obstructive sleep apnea collar 10 in position. Also shown is optional feedback positioning button 102. The use of button 102 provides patient 100 with positive verification that collar 10 has been properly positioned. Button 102 is depressed by patient 100 to activate the muscle stimulation signal from electronic module 20. If collar 10 is properly positioned, patient 100 will notice a contraction of the muscles associated with his upper air passageway.

FIG. 6 is a schematic view of electronic module 20 showing its major components. Electronic circuit 200 is powered by primary battery 104 which may or may not be included in the collar. Electronic circuit 200 is preferably a custom integrated circuit, but more probably is a hybrid.

Electronic circuit 200 may or may not be included in the collar and has one input cable 30 from sensor 24 and two output cables 32 and 34 coupled to electrodes 26 and 28, respectively (see also FIG. 1). Referring again to FIG. 6, input cable 30 terminates at terminals 112 and 114. Similarly, output cable 32 terminates at terminal 108 and output cable 34 terminates at terminal 110.

FIG. 7 is a block diagram of electronic circuit 200. Each of the components of electronic circuit 200 is readily available in commercial form. Cable 30 from sensor 24 (see also FIGS. 1 and 6), transfers the sensor signal via terminals 112 and 114 to In amp 202, which provides initial amplification. Bandpass filter 204 filters the amplified sensor signal to obtain the desired pass band. For sensor 24 as a breath or snoring activity sensor, for example, the desired passband of bandpass filter 204 is approximately from 20 to 200 hertz.

The filtered signal is presented to full wave rectifier 205 and then to integrator 206 which integrates the signal over the appropriate time. For sensor 24 as an audio sensor, one-third of a second is an appropriate integration time as determined by reset timer 211. The output of integrator 206 is a level representing the integrated sensor signal. This level is presented to threshold detector 207 having the threshold value set by threshold adjust 216. This ensures that whenever the integrated level exceeds the threshold set by threshold adjust 216, a signal is set to on-time timer 208 which initiates a ramp signal from ramp generator 209 for the duration as set by trigger adjust 212.

Stimulation signals are produced by pulse generator 210 having an amplitude set by the output of ramp generator 209. The amplitude of these pulses is set by amplitude adjust 213. The on-set of these pulses is slowly ramped up in amplitude by ramp

generator 209. These signals are appropriate to stimulate contraction of the genioglossus and related muscle groups. The preferred stimulation frequency is 30 to 60 pulses per second. On-time timer 208 ensures that the stimulation bursts are at least a predetermined minimum duration. As explained above, button 102 is a single pole/single throw push button used to manually activate pulse generator 210. This manual activation permits patient 100 to verify proper positioning of collar 10.

The output of pulse generator 210 is coupled to step-up transformer 214 which provides the appropriate voltage necessary to drive electrodes 26 and 28 via cables 32 and 34, respectively.

Having thus described the preferred embodiments of the present invention, those of skill in the art will be readily able to apply the teachings found herein to yet other embodiments without departing from the scope of the claims hereto attached.

WE CLAIM:

1. An apparatus for treating obstruction of an upper air passageway of a patient comprising:

a. means for sensing the onset of an obstructive sleep apnea episode;

b. means coupled to said sensing means for generating muscle stimulating signals;

c. electrode means coupled to said generating means for transcutaneously transferring said muscle stimulating signals to clear said upper air passageway of said patient; and

d. means attached to said sensing means, said generating means, and said electrode means for maintaining said sensing means, said generating means, and said electrode means in proximity with said patient.

2. An apparatus according to claim 1 further comprising means coupled to said maintaining means for positioning said maintaining means with respect to said patient.

3. An apparatus according to claim 2 wherein said maintaining means further comprises a collar.

4. An apparatus according to claim 3 wherein said sensing means further comprises an audio sensor.

5. An apparatus according to claim 3 wherein said sensing means further comprises an activity sensor.

6. An apparatus according to claim 3 wherein said sensing means further comprises an oximeter.

7. An apparatus according to claim 3 wherein said sensing means further comprises an air flowmeter.

8. An apparatus according to claims 2, 3, 4, 5, 6, or 7 wherein said positioning means further comprises a unique shape.

9. An apparatus according to claims 2, 3, 4, 5, 6, or 7 wherein said positioning means further comprises a unique color.

10. An apparatus according to claim 8 wherein said unique shape further comprises a chin notch.

11. An apparatus according to claim 8 wherein said unique shape further comprises at least one shoulder notch.

12. An apparatus according to claim 8 further comprising means coupled to said generating means for verifying proper placement of said maintaining means.

13. An apparatus according to claim 9 further comprising means coupled to said generating means for verifying proper placement of said maintaining means.

14. An apparatus according to claim 10 further comprising means coupled to said generating means for verifying proper placement of said maintaining means.

15. An apparatus according to claim 11 further comprising means coupled to said generating means for verifying proper placement of said maintaining means.

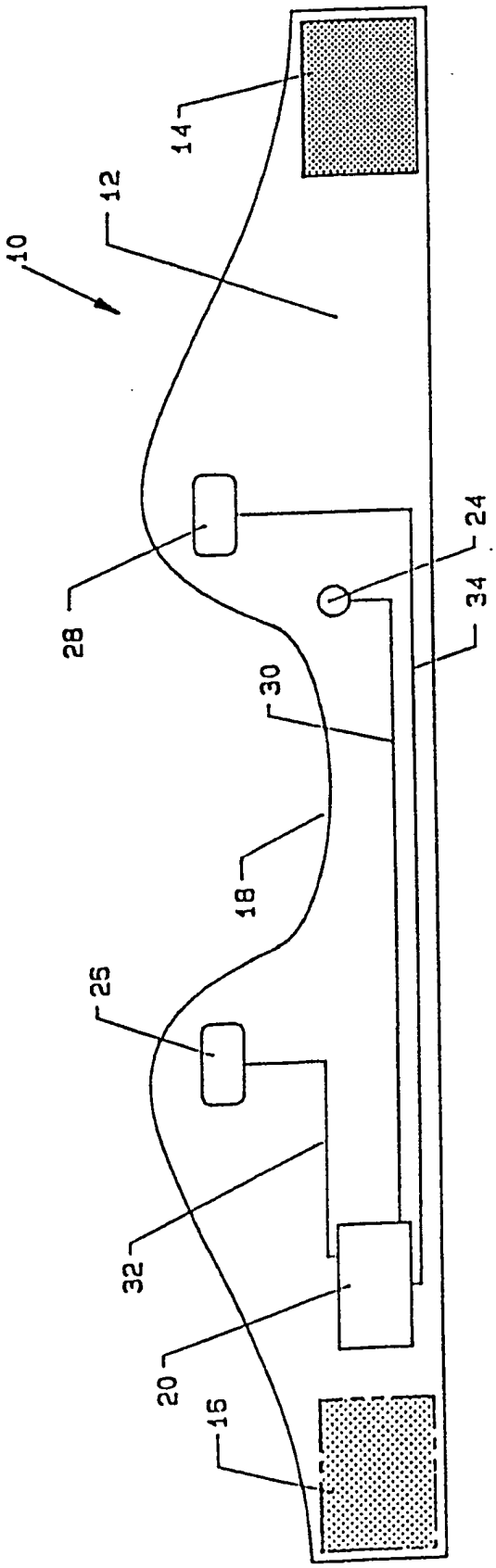

FIG.1

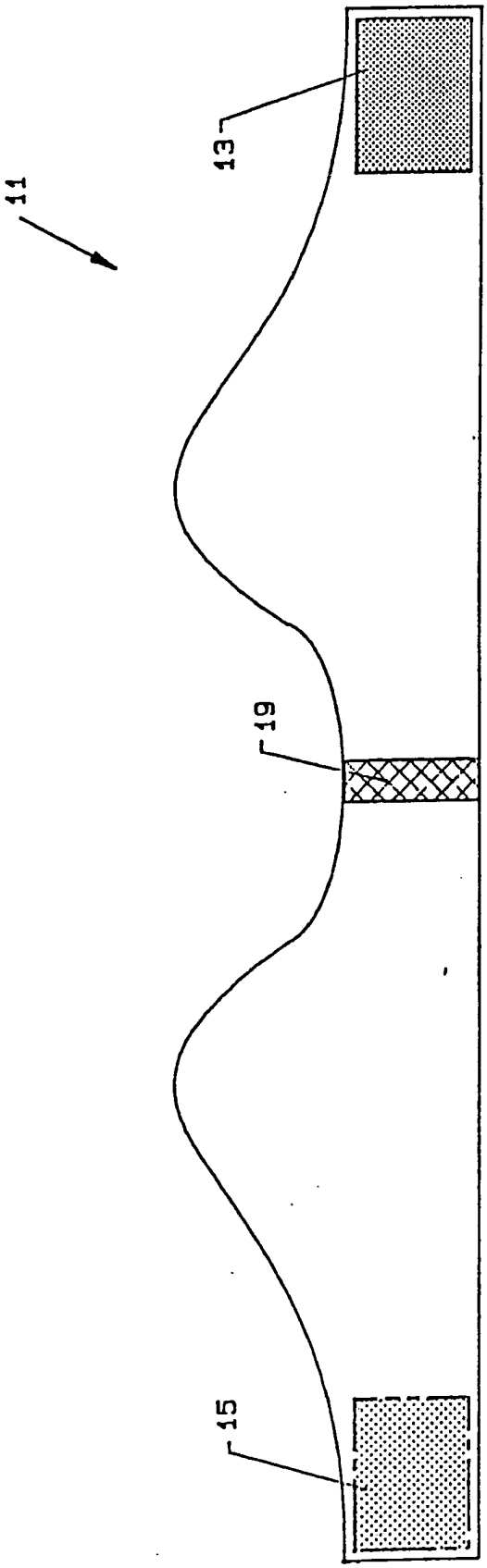

FIG. 2

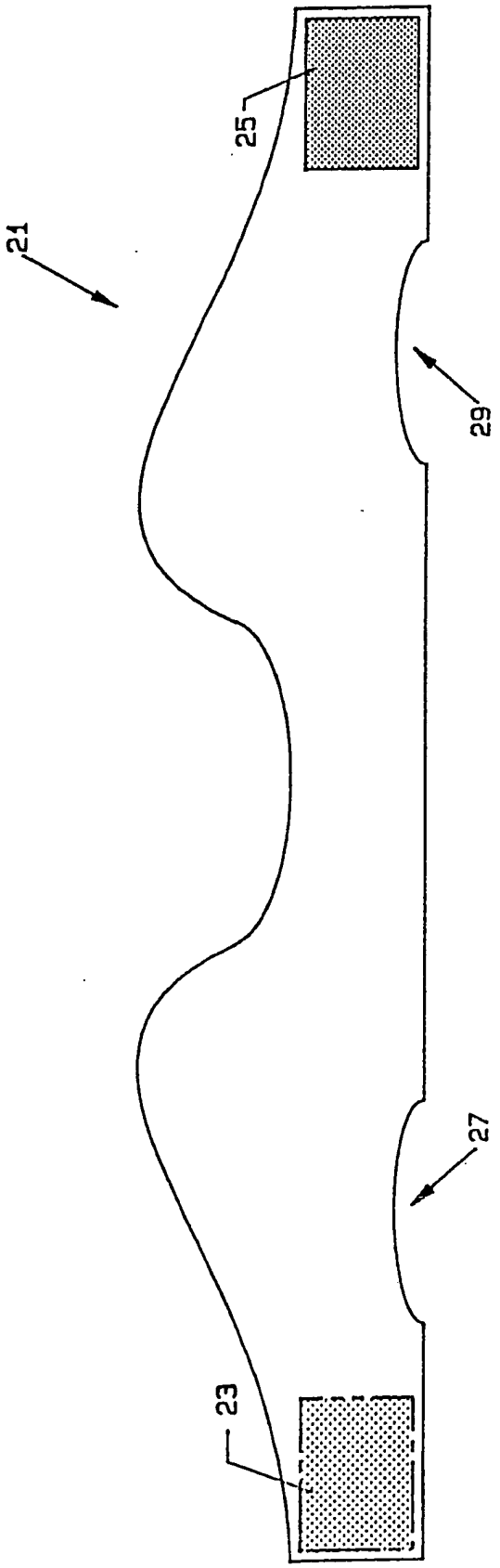

FIG. 3

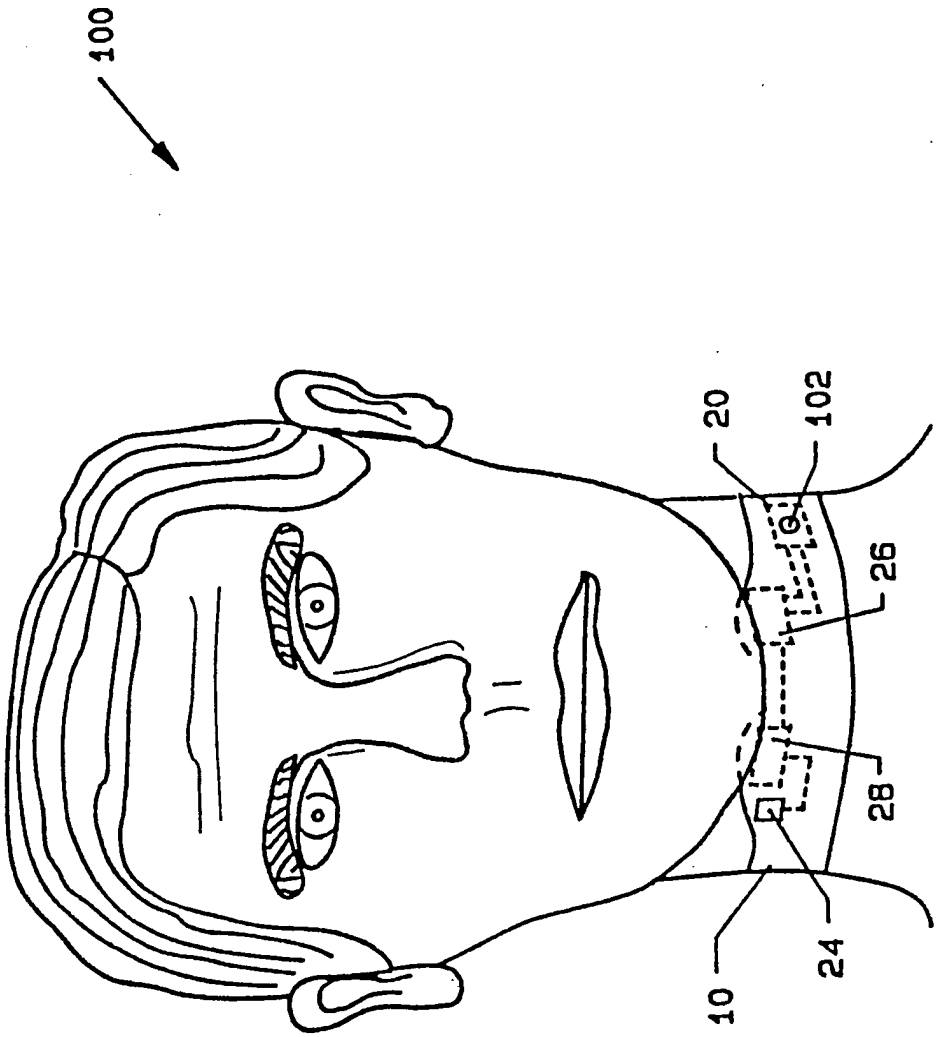

FIG. 4

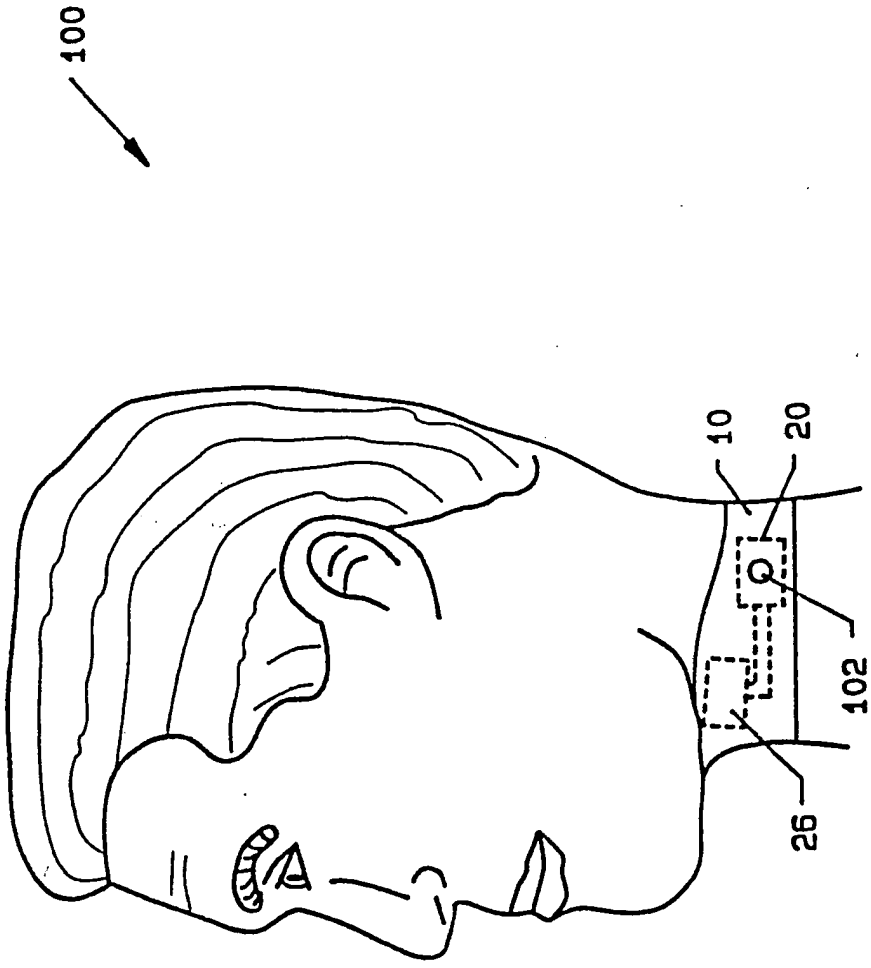

FIG. 5

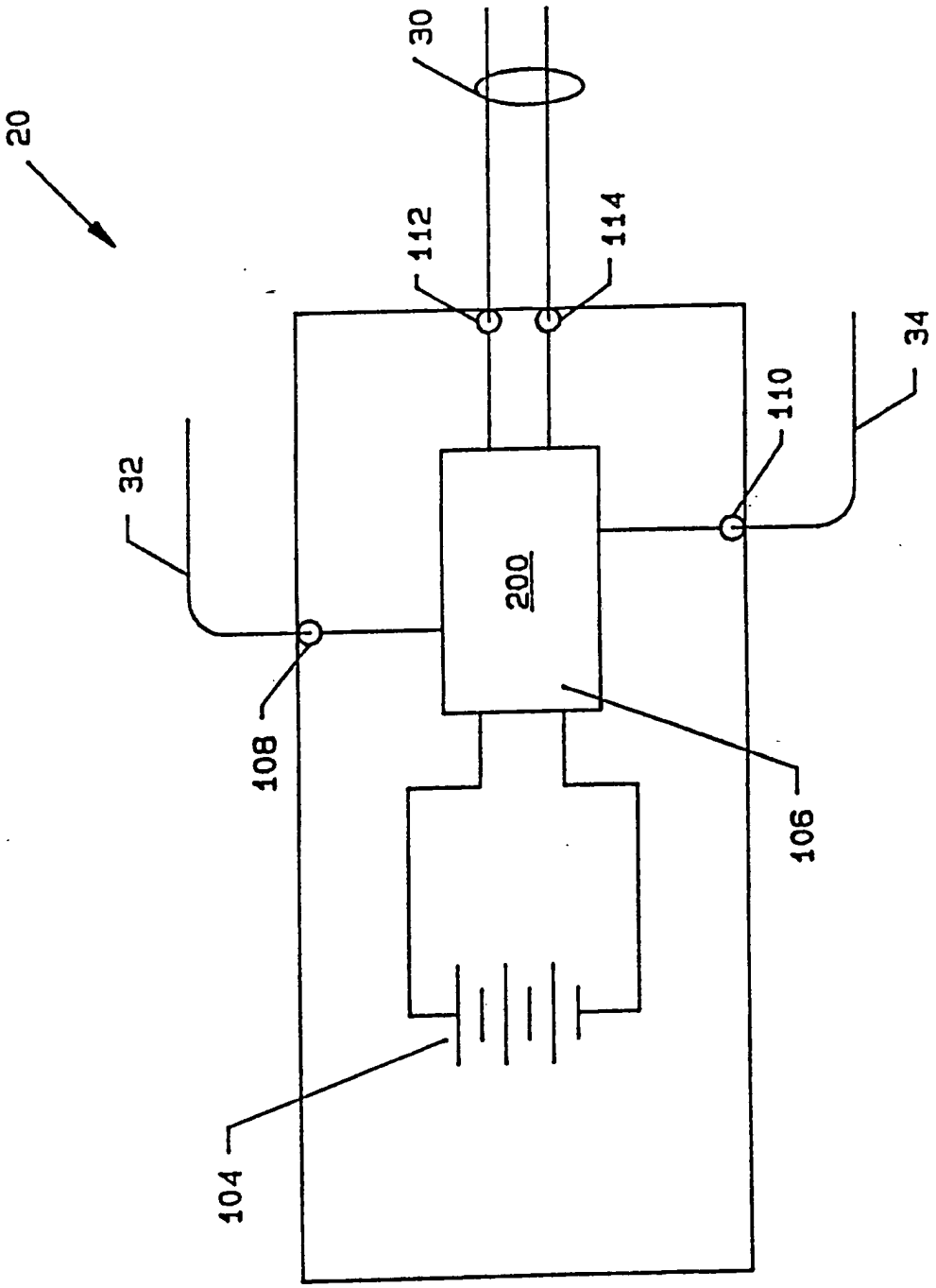

FIG. 6

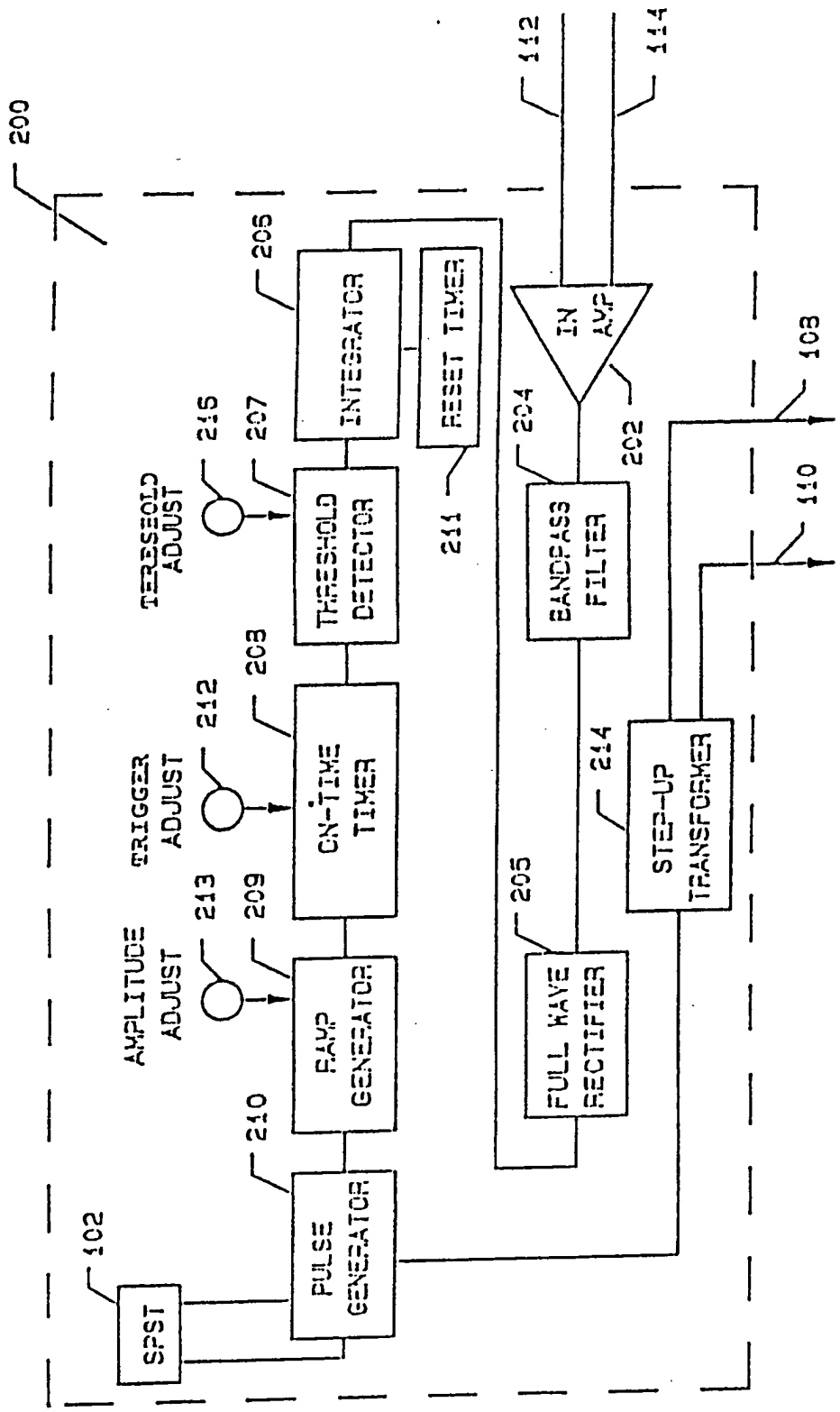
200
102
SPST
PULSE GENERATOR
210
RAMP GENERATOR
209
AMPLITUDE ADJUST
213
ON-TIME TIMER
203
TRIGGER ADJUST
212
THRESHOLD DETECTOR
207
THRESHOLD ADJUST
215
INTEGRATOR
205
RESET TIMER
211
FULL WAVE RECTIFIER
205
BANDPASS FILTER
204
IN AMP
202
STEP-UP TRANSFORMER
214
112
114
108
110

FIG. 7

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US91/05820

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [5]

According to International Patent Classification (IPC) or to both National Classification and IPC

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U.S. CL: 121/859

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
U.S. CL:	128/846,848,859,860,724,733,773,774,777; 340/573,575,626,665,668

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
X Y	US, A, 4,715,367 (CROSSLEY) 29 December 1987. See the entire document.	1-5, 7-8 9
A	US, A, 3,480,010 (CROSSLEY) 25 November 1969. See the entire document.	1-15
A	US, A, 4,440,160 (FISCHELL ET AL.) 03 April 1984. See the entire document.	1-15
A	US, A, 4,220,142 (ROSEN ET AL.) 02 September 1980. See the entire document.	1-15
A	US, A, 3,998,209 (MACVAUGH) 21 December 1976. See the entire document.	1-15
A	US, A, 4,669,477 (OBER) 02 June 1987 See the entire document.	1-15

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
13 SEPTEMBER 1991	17 OCT 1991
International Searching Authority	**Signature of Authorized Officer**
ISA/US	MICHAEL A. BROWN

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(71) Applicant *(for all designated States except US)*: MINNESOTA INNOVATIVE TECHNOLOGIES & INSTRUMENTS CORPORATION (MITI) [US/US]; 738 Country Lakes Drive, Lino Lakes, MN 55014–5488 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: SCHMIDT, Matthew, F. [US/US]; 738 Country Lake Drive, Lino Lakes, MN 55014–5488 (US). BUAN, John, S. [US/US]; 15412 64th Place North, Maple Grove, MN 55311 (US). NORDMAN, Catherine, A. [US/US]; 1875 Selby Avenue, St. Paul, MN 55104 (US).

(74) Agent: RAASCH, Kevin, W.; Mueting, Raasch & Gebhardt, P.A., P.O. Box 581415, Minneapolis, MN 55458–1415 (US).

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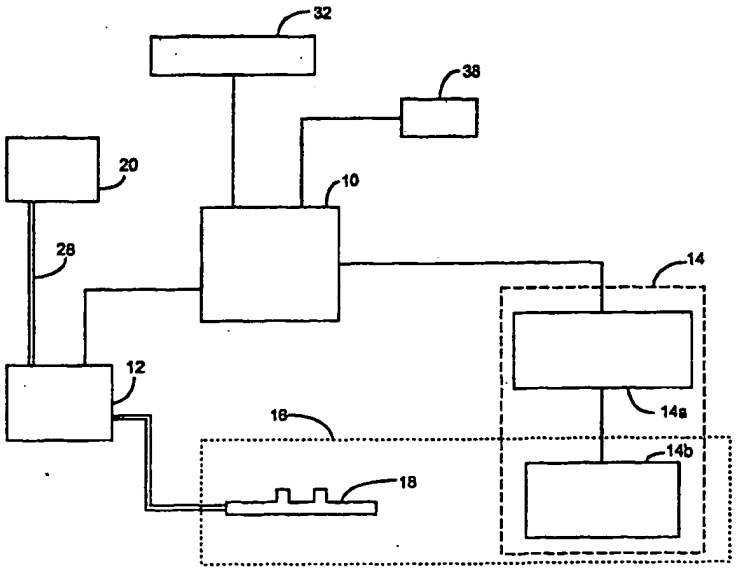
(54) Title: CONTROL DEVICE FOR SUPPLYING SUPPLEMENTAL RESPIRATORY OXYGEN



(57) Abstract

Methods and systems for supplying supplemental oxygen to patients for use in sub–acute care which maintain healthy blood oxygen content in the patients by controlled dosing of oxygen with a measured response to the patient's actual blood oxygen content are disclosed. The dosing can be provided by simple ON/OFF control over the delivery of oxygen or the amount of oxygen delivered to the patient with each inhalation can be varied in response to the patient's need as determined by a more sophisticated control scheme, such as a PID loop control algorithm, that utilizes the difference between the patient's actual blood oxygen content and a target blood oxygen content and/or trends in the blood oxygen content. The systems and methods are particularly directed at patients receiving supplemental oxygen in a sub–acute care environment.

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CONTROL DEVICE FOR SUPPLYING SUPPLEMENTAL RESPIRATORY OXYGEN

The present invention relates to the field of supplemental respiratory oxygen supply systems and methods. More particularly, the present invention provides methods and systems that conserve supplemental respiratory oxygen.

Background

A large patient community is currently undergoing oxygen therapy at home or in long-term care facilities, such as nursing homes. Supplemental respiratory oxygen has been a widely accepted form of treatment for COPD (chronic obstructive pulmonary disease) patients with hypoxemia following the completion of a major National Institutes of Health study in 1980. The Nocturnal Oxygen Therapy Trial established the efficacy of continuous oxygen therapy in the extension of the life span of sufferers of COPD with chronic hypoxemia.

For administration of long-term oxygen therapy it has been common practice to deliver the oxygen directly into the nostrils of the patient through a device known as a nasal cannula. The cannula is connected via a supply hose to a source of oxygen, such as an oxygen concentrator, liquid oxygen dewar or high pressure gas cylinder. The oxygen is delivered continuously to the patient at a rate prescribed by a physician.

It has been recognized that continuous oxygen delivery is wasteful of oxygen, as a patient needs oxygen only when they are inhaling and the oxygen delivered at other times is wasted. The most significant financial cost associated with this waste is found in the increased service visits required by the oxygen provider to replenish the patient's oxygen supply, because the actual cost of the oxygen is only a small fraction of the total cost of the therapy.

Another problem associated with supplemental oxygen therapy is that the physical size and weight of the oxygen apparatus can reduce the patient's mobility.

A number of approaches have been taken to address the problems of waste, cost and portability of oxygen therapy. The therapeutic approach that has grown out of this body of work is typically referred to as "demand delivery." The devices respond to a patient's inspiratory effort by delivering a predetermined pulse of oxygen during the period of inhalation, rather than allow the oxygen to flow to the patient continuously. There are many ways in which this basic concept has been implemented.

Extensive work has been done on sensors, timing of oxygen release, and algorithms for delivery of the oxygen. A variety of methods for sensing the respiratory cycle have been used, including pressure sensors that are in fluidic communication with the patient's airway, flow sensors, and chest belts which detect the movement of the thorax during respiration. Some systems deliver a small bolus of oxygen at the beginning of inhalation, while others deliver continuous flow throughout inhalation. There has also been work on the frequency of delivery. For example, some systems do not provide oxygen at every breath.

In spite of the large variety of approaches taken to conserve oxygen supplies and/or reduce the size and weight of the oxygen supply equipment, no consensus has yet been reached as to the most appropriate way to save oxygen and medicate the patient adequately.

The simplest approaches to conserve oxygen involve detection of inhalation as a trigger to deliver oxygen. A variety of detection devices were developed in pursuit of this basic approach to controlling oxygen supply, including a chest belt worn by the patient that generates an electrical signal to trigger the opening of the oxygen supply valve; a hand-activated breathing device attached to a portable gas bottle via a supply hose in which users would dispense the oxygen by pushing a button while holding the device next to their mouth; a mechanical chest strap/valve

that functions as both an inhalation sensor and delivery device in an oxygen conserving system; and an all-pneumatic, fluidically-controlled device.

Another approach uses pressure sensors in the oxygen line to monitor line pressure at the nostrils. A small negative pressure, indicative of the onset of inhalation, triggers the release of oxygen. This type of detection scheme has become the standard method and is employed by most systems currently in use. The systems attempt to provide a physiologically equivalent dose of oxygen, when compared to continuous flow, by providing a burst of oxygen at the onset of inhalation. By providing more oxygen at the beginning of inhalation, when it is more physiologically useful, the most efficient of these systems claim to be able to reduce oxygen consumption.

The existing demand delivery devices provide economic benefit in the form of oxygen savings (and reduced service visits), but it is often at the expense of the level of medical care. In particular, some patients have been found to have deficient levels of oxygen in their blood as a result of using known demand delivery devices. Certain activities, such as exercise and sleep, cause the body's need for oxygen to fluctuate in an unpredictable manner. The chronic hypoxemia being corrected by the prescription of oxygen therapy is not fully ameliorated by these devices.

Because demand delivery devices and continuous flow systems do not measure the patient's blood oxygen saturation, they do not respond to a change in patient need as would be indicated by a drop in oxygen saturation. The oxygen flow in the form of pulses of gas is fixed in some devices, such as the PulseDose by DeVilbiss, as it is delivered with every breath. In other devices, such as the Oxymatic 301 from Chad Therapeutics, the patient is allowed some adjustability in the flow by determining the frequency of pulses as a function of the number of breaths; i.e., one pulse every fourth breath, a pulse every other breath, etc. None of these types of demand delivery system is capable of directly addressing fluctuations in the blood oxygen level experienced by the user.

In fact, while it is generally known that existing modes of oxygen therapy are inadequate for most patients at least some of the time (that is, acute periods of hypoxia, SaO_2<88%, can be seen in virtually all patients for some fraction of each day), another problem that is not addressed by the known devices and methods is that the average COPD patient is receiving more oxygen than needed for a significant part of each day. For example, the oxygen patients studied by Decker, et al. (Chest 1992) had an SaO_2 greater than 90% for more than 70% of the time they spent breathing room air without any supplemental oxygen. In another study of even sicker patients (Sliwinski, et al., European Respiratory Journal 1994), SaO_2 was greater than 88% for 40% of the time while breathing room air, and greater than 92% (higher than necessary) for about 70% of the time they were using their supplemental oxygen. The lack of methods and/or systems for controlling the upper limit of blood oxygen content results in significant amounts of wasted oxygen.

Devices which control the flow of oxygen based on blood oxygen measurements from various types of sensors have been described for a variety of applications. However, none of these devices were meant for residential use by sub-acute COPD patients, none had the goal or object of conserving as much oxygen as possible while still maintaining a healthy blood oxygen level, and none used a pulsed, demand-delivery method for conserving oxygen.

Measurements of blood oxygen saturation can be broken into two groups of measurement strategies: invasive and non-invasive. An invasive measurement using existing technology requires that blood be drawn from the body and the sample placed in a blood gas analyzer. One common non-invasive blood oxygen sensor is a pulse oximeter which relies on the differences in the light absorption curves of saturated and desaturated hemoglobin in the infrared and near-infrared portions of the spectrum. The typical pulse oximeter sensor includes two LED's, one red and one infrared. As the light from the two LED's passes through a capillary bed at the point of attachment, such as is found on the finger, the light is partially absorbed by the blood and tissues and then is detected by a photodetector. The electrical signal

generated by the photodetector, which is proportional to the amount of light absorbed by the body, is transmitted to the oximeter. The absorption measurements can be made rapidly, up to 500 times per second for each LED. Because of the pulsatile nature of arterial blood, the absorption as a function of time will vary slightly at the frequency of the pulse. This allows the oximeter to extract the arterial blood oxygen saturation information from background noise caused by absorption in tissues located between the LED's and the photodetector. Pulse oximetry is a well-accepted technique and can be found in machines used for monitoring patients under anesthesia, patients participating in sleep studies and neonatal monitoring.

Some methods and systems for controlling oxygen delivery to patients in critical care settings have been disclosed. Some of the systems use feedback loop controllers that use the blood oxygen saturation signal, SpO_2, from a pulse oximeter to control the inspired oxygen fraction (FIO_2) in the respiratory gas delivered by a mechanical ventilator in which oxygen is mixed with air to supply an accurate amount of oxygen to a patient through a mask or hood. These systems are intended for the care of critically ill patients receiving treatment in hospitals for severe respiratory distress caused by a chronic condition or accident.

Summary of the Invention

The present invention provides supplemental respiratory oxygen supply methods and systems which maintain healthy blood oxygen saturation in sub-acute patients receiving supplemental oxygen by controlling the dosing of oxygen with a measured response to the patient's actual blood oxygen saturation levels. This closed-loop control of oxygen flow for COPD patients provides for both healthy blood oxygen levels and significant oxygen conservation by reducing or preventing the delivery of supplemental respiratory oxygen during those times when the patient has a desired blood oxygen level.

In one aspect, the present invention provides a method of controlling supplemental oxygen delivery during sub-acute care by continuously measuring

blood oxygen content of a patient to obtain a measured blood oxygen content level; delivering supplemental oxygen from an oxygen source to the patient when the patient is inhaling if the measured blood oxygen content level is below a desired value; and restricting the delivery of supplemental oxygen if the measured blood oxygen content level of the patient is above the desired value.

In another aspect, the present invention provides a method of controlling supplemental oxygen delivery for sub-acute care by continuously measuring blood oxygen content of a patient to obtain a measured blood oxygen content level; sensing variations in respiration of the patient to determine when the patient is inhaling; delivering supplemental oxygen from an oxygen source to the patient through a supplemental oxygen delivery device when the patient is inhaling if the measured blood oxygen content level is below a desired value; and restricting the delivery of supplemental oxygen to the patient through the supplemental oxygen delivery device if the measured blood oxygen content level of the patient is above the desired value.

In another aspect, the present invention provides a method of controlling supplemental oxygen delivery for sub-acute care by continuously measuring blood oxygen content of a patient to obtain a measured blood oxygen content level; delivering a variable dose of supplemental oxygen from an oxygen source to the patient when the patient is inhaling, wherein the variable dose is at least partially determined based on the measured blood oxygen content level.

In another aspect, the present invention provides a method of controlling supplemental oxygen delivery for sub-acute care by continuously measuring blood oxygen content of a patient to obtain a measured blood oxygen content level; sensing variations in respiration of the patient to determine when the patient is inhaling; delivering a variable dose of supplemental oxygen from an oxygen source to the patient through a supplemental oxygen delivery device when the patient is inhaling, wherein the variable dose of supplemental oxygen is at least partially based on a difference between the desired value for the measured blood oxygen content level and the measured blood oxygen content level.

In another aspect, the present invention provides a method of sensing variations in respiration of a patient by providing a flow sensor in fluid communication with the respiratory flow of a patient; monitoring the flow sensor to determine when the patient is inspiring air; and monitoring the flow sensor to determine when the patient is expiring air.

In another aspect, the present invention provides a demand delivery method for controlling the delivery of oxygen to a patient by providing a flow sensor in fluid communication with the respiratory flow of a patient; monitoring the flow sensor to determine when the patient is inhaling; delivering oxygen to the patient when the patient is inhaling; monitoring the flow sensor to determine when the patient is exhaling; restricting delivery of oxygen to the patient when the patient is exhaling.

In another aspect, the present invention provides a system for delivering supplemental oxygen for sub-acute care, the system including a blood oxygen content level sensor; a source of supplemental oxygen; a valve in fluid communication with the source of supplemental oxygen; and a controller capable of operating the valve, the controller restricting flow through the valve when the blood oxygen content level measured by the blood oxygen content level sensor is above a desired value.

In another aspect, the present invention provides a system for controlling supplemental oxygen delivery including means for measuring blood oxygen content level of a patient; means for delivering supplemental oxygen from an oxygen source to the patient when the patient is inhaling if the measured blood oxygen content level is below a desired level; and means for restricting the delivery of supplemental oxygen from the oxygen source to the patient if the measured blood oxygen content of the patient is above a desired level.

In another aspect, the present invention provides a system for controlling supplemental oxygen delivery including means for measuring blood oxygen content level of a patient; and means for delivering a variable dose of supplemental oxygen from an oxygen source to the patient when the patient is inhaling, wherein the

variable dose is at least partially determined based on the measured blood oxygen content.

As used in connection with the present invention, the terms "supplemental oxygen" and "supplemental respiratory oxygen" refer to oxygen delivered to patients in addition to the oxygen received by the patient through the inspiration of room or ambient air. Because room air contains some oxygen, the supplemental oxygen is provided in addition to the oxygen that would normally be inspired by the patient.

As used in connection with the present invention, the term "blood oxygen content" and "blood oxygen content level" will typically be used to refer to blood oxygen saturation as commonly measured by the percentage of oxygen-saturated hemoglobin (SpO_2) although it can also refer to any suitable measurement for determining the level of oxygenation in a patient's blood. For example, it will be understood that blood oxygen content can also be obtained based on data from a CO-oximeter. Furthermore, blood oxygen content, can also be obtained based on partial pressures of oxygen (PaO_2).

As used in connection with the present invention, the term "sub-acute care" refers to care provided to patients that is not intended to treat critical conditions. Typically, sub-acute care is provided to patients in residential settings. "Residential" preferably includes, e.g., homes and long-term care facilities (such as nursing homes). Sub-acute care also includes care delivered in ambulatory situations, i.e., when the patient is engaged in normal activities outside of his or her residence, such as shopping, attending concerts or other events, traveling to appointments with health care professionals, etc.

As used in connection with the present invention, the terms "continuous" and "continuously" (when referring to the measuring of blood oxygen content levels) mean that the blood oxygen content level of the patient will be measured without cessation or at intervals (fixed or variable) that are sufficiently small to provide the advantages of the invention.

These and other features and advantages of the present invention will be apparent upon review of the detailed description of the invention and accompanying drawings.

Brief Description of the Drawings

FIGURE 1 is a block diagram of one system according to the present invention.

FIGURE 2 is a block diagram of one demand delivery module for use in a system such as that depicted in Figure 1.

FIGURE 3a is a flow diagram of one method according to the present invention.

FIGURE 3b is a flow diagram of another method according to the present invention.

FIGURE 4 is a flow diagram of one method of delivering supplemental oxygen based on whether the measured blood oxygen content data is valid or invalid.

Detailed Description of Illustrative Embodiments of the Invention

As described above, the present invention provides demand respirating oxygen supply methods and apparatus for use in sub-acute care which maintain healthy blood oxygen saturation in patients by controlled dosing of oxygen with a measured response to the patient's actual blood oxygen content. The dosing can be provided by simple on/off control over the delivery of oxygen or the amount of oxygen delivered to the patient with each inhalation can be varied in response to the patient's need as determined by a more sophisticated control scheme, such as a proportional-integral-derivative (PID) loop control algorithm, that utilizes the difference between the patient's measured blood oxygen content level and a desired or target blood oxygen content level.

The systems and methods of the present invention are particularly directed at patients receiving supplemental oxygen in a sub-acute care environment, more

preferably in a residential setting. The needs and considerations of patients receiving supplemental oxygen in sub-acute care differ from those present when providing oxygen to patients in critical care environments, in which the amounts of oxygen delivered to patients are carefully controlled in connection with masks or other enclosures that do not typically allow the patents to inspire room air in uncontrolled manners. In those situations, the fractional amount of inspired oxygen (FIO_2) is typically controlled by mixing oxygen and air in a blender or other device before delivering the gas to the patient.

Among the advantages of the present invention are the significant conservation of oxygen provided by delivering only the amount of oxygen needed to maintain a healthy blood oxygen content and the ability to address therapeutic problems associated with demand delivery systems by providing the correct amount of oxygen to the patient to reduce uncontrolled hypoxic events.

The amounts of oxygen that can be conserved by implementing the methods according to the present invention can be significant, even compared to known demand delivery systems that conserve oxygen by simply turning the supply on or off during a patient's respiration. Studies have reported oxygen savings ratios of from 3:1 to 7:1 for known simple demand delivery systems. In other words, a fixed amount of oxygen can last three to seven times as long as the same amount of oxygen would last in a supplemental oxygen delivery system that does not include a simple demand delivery system. Implementation of the methods according to the present invention by using a demand delivery approach with a feedback control mechanism that responds to a continuous blood oxygenation measurement could provide an oxygen savings ratio of greater than 13:1 while maintaining the patient's SaO_2 at the 90% level.

Other advantages of the methods and apparatus according to the present invention are the ability to integrate the invention with any sub-acute care supplemental oxygen supply system, including both ambulatory and stationary sources. For unlimited volume sources, such as oxygen concentrators and membrane

separators, the invention will reduce their size and energy consumption for a given level of therapy. For fixed volume gas sources, such as liquid and high pressure gas, the invention will extend the lifetime of the oxygen supply, thereby significantly decreasing the cost of providing that treatment.

If the system is ambulatory, the present invention can allow for reductions in the size and weight of the oxygen source, thereby increasing the patient's mobility. An added benefit of reducing the size and/or weight of the ambulatory systems is the potential for a better therapeutic outcome. If patients find the smaller, lighter weight systems less cosmetically unattractive they will be more likely to carry and use the systems during ambulatory activities as opposed to not using the systems. Studies have shown that the benefit of supplemental oxygen systems is significantly reduced if the systems are not used on a regular basis.

Another advantage of the invention, method and apparatus, is a reduction in the risk of hypercapnia (carbon dioxide retention) by only providing enough oxygen to reach a predetermined blood oxygen saturation, typically about 90% as measured by a conventional two-color pulse oximeter.

One embodiment of an automated respiratory oxygen supply system is depicted in Figure 1 and includes a controller 10, a demand delivery module 12, and a blood oxygen content sensor 14 connected to the patient 16. Oxygen is supplied from an oxygen source 20 to the patient 16 by the demand delivery module 12 through, in the preferred embodiments, a supplemental oxygen delivery device 18. The preferred system may also include a user interface 32 and an alarm 38.

The supplemental oxygen delivery device 18 is preferably a nasal cannula as depicted in Figure 1, although it will be understood that the supplemental oxygen delivery device can take the form of any device designed to provide supplemental respiratory oxygen to a patient while not preventing the patient from also inspiring room or ambient air in addition to the supplemental respiratory oxygen from an oxygen source. Examples of other supplemental oxygen delivery devices include, but are not limited to: tracheal catheters, nasal masks designed for use with Continuous

Positive Airway Pressure (CPAP) systems, vented masks that cover both the nose and the mouth but that allow inspiration of room air in uncontrolled amounts in addition to the supplemental oxygen delivered to the mask, etc.

Oxygen source 20 could be an oxygen concentrator, membrane separator, high pressure cylinder or liquid oxygen dewar. This could also include any portable versions of oxygen sources 20. Other potential sources of oxygen gas suitable for providing supplemental oxygen in sub-acute care in a residential setting and/ambulatory situations may be created in the future and should be considered as being functional with the described invention. As used below, "line" will refer to any connection made between the oxygen source, the described invention and the patient.

If the oxygen source 20 is an oxygen concentrator, typically a continuous low-flow device, usually delivering at most 6 liters/min of 96% oxygen, the system may also include an oxygen storage device to accommodate the periodic higher flows that are necessary to practice the methods described below. If high flow concentrators become available, such a storage device would not be needed.

One controller 10 is an electronic circuit including a software programmable microcontroller as its main component. Depending on the allocation of tasks within the device a number of microcontrollers could be used as a controller 10. In one embodiment, the controller 10 includes a serial data input port, A/D converter, LED driver capabilities and digital I/O pins. One example of a suitable controller is the PIC 16C74A microcontroller from Microchip Technology Inc. of Chandler, Arizona.

Those skilled in the art will realize that a great deal of optimization may be done relative to the choice of a microcontroller(s). Specifications, such as power consumption, cost, memory size, clock speed and part availability may alter the choice for a preferred microcontroller. Furthermore, many of the functions described for the microcontroller in the preferred embodiment could be accomplished by using discrete circuits of many types. Additionally, the microcontroller and its peripheral circuitry may be replaced entirely by discrete circuitry, such as programmable logic arrays, A/D converter chips, analog comparators, etc.

The system also includes an oxygen content sensor 14 for monitoring the blood oxygen content of the patient 16. One suitable sensor 14 includes a sensor control module 14a and a sensor 14b typically mounted or attached to the patient 16 by some suitable technique. The information from the oxygen content sensor 14 is fed back to the controller 10 for use in executing the methods according to the present invention. It is preferred, but not required, that the oxygen sensor 14 provide a signal to the system controller 10 in the form of a blood oxygen saturation in percent. The sensor 14 preferably, but not necessarily, processes all of its data internally and the controller 10 preferably processes only error flags and numerical information as described shortly.

One preferred oxygen sensor 14 is a non-invasive sensor such as a two-color pulse oximeter. As used herein, the terms "pulse oximeter" or "oxygen sensor" will include both the optical sensor and the circuitry used to determine blood oxygen saturation levels using the optical sensor. One example of a suitable pulse oximeter is a conventional two-color, OEM-II oximeter module, from Nonin Medical Inc. of Plymouth, MN, that can measure the percentage of oxygen-saturated hemoglobin, SpO_2, in the blood stream of an in vivo respiratory system. The preferred embodiment of the pulse oximeter 14 uses a transmitting sensor that attaches to the user's finger. Alternative embodiments may employ sensors that attach elsewhere on the body.

While the pulse oximeter is one preferred non-invasive oxygen sensor, it should be understood that any blood oxygen sensor, invasive or non-invasive, useful for determining blood oxygen content levels (preferably continuously) could be used in connection with the present invention. It should also be apparent to those skilled in the art that technologies on the horizon, such as an implantable, micro-electromechanical (MEMS) blood gas analyzer, may provide the blood oxygen content information needed by the system controller 10. Furthermore, there may be improvements in pulse oximetry technology, such as the ability to determine the level of carboxyhemoglobin in the blood, that may be useful for the described invention.

Use of these new blood oxygen content technologies in oxygen conservers for long-term oxygen therapy should be considered to lie within the scope of the systems and methods of the present invention provided they have the ability to provide suitable blood oxygen content measurements.

In one embodiment, the pulse oximeter 14 deconvolves the optical information into a blood oxygen saturation value, SpO_2, in percent. The oximeter 14 outputs a serial data stream with this information to the controller 10 for evaluation. Other important information may also be included in the oximeter data stream, such as the user's pulse rate and error flags that detail the reliability of the SpO_2 and pulse rate values.

It will be recognized by those skilled in the art that an alternative embodiment may be provided in which the system controller 10 functions as the sensor control module 14a. As a result, data evaluation and error handling would be accomplished within the system controller 10 with an appropriate oxygen sensor 14b being attached to the patient 16.

Blood oxygen content measuring in connection with the present invention is described as "continuous" although it will be understood that the measurements made using, e.g., pulse oximeters and other devices, may actually be taken at discrete intervals. As discussed above, "continuous" as used in connection with the measuring of blood oxygen content in the present invention includes measurement of the blood oxygen content levels of the patient at intervals (fixed or variable) that are sufficiently small to provide the advantages of the invention. Preferably the sampling intervals will be less than about five minutes, more preferably less than about one minute, and even more preferably less than about one respiration interval (i.e., the time between the onset of two inhalations by the patient).

The information relating to blood oxygen content provided by the oxygen sensor 16 is then used by the system controller 10 in combination with the demand delivery module 12 to provide control over the oxygen supplied to the patient 16

from the oxygen source 20 as described in connection with the methods according to the present invention below.

A block diagram illustrating the components of one embodiment of a demand delivery module 12 according to the present invention is depicted in Figure 2. One component in the demand delivery module 12 is an inhalation or respiration sensor 40 that monitors the respiratory activity of the patient 16 to determine variations in respiration of the patient. It is preferred that the variations in respiration allow the determination of when the patient is inhaling, although other portions of the respiratory cycle may actually be sensed. In other words, inhalation is preferably sensed, but in some cases it may be desirable to determine when inhalation is occurring based on the sensing of some other condition, activity, etc. such as chest movement, exhalation, etc.

In one embodiment, the respiration sensor 40 provides a signal to a respiration sensor/valve controller 42 that, in turn, controls the valve 26 based on additional input from system controller 10 (as will be described in more detail below).

The respiration sensor 40 can take a variety of forms that will be known to those skilled in the art. One type of suitable respiration sensor 40 monitors flow in the line used to supply oxygen to the supplemental oxygen delivery device 18. The sensor 40 in Figure 2 monitors flow through the valve 26 interposed in the line between the supplemental oxygen delivery device 18 and the oxygen source 20. One suitable flow sensor is a Honeywell AWM2150 Microbridge Mass Airflow Sensor (available from Honeywell Corp., Minneapolis, Minnesota).

Another feature of the preferred respiration sensor 40 is the ability to sense bidirectional flow, i.e., flow in each direction through the sensor 40. It is preferred that the flow generated by inhaling causes a voltage output of one polarity from the sensor 40, while flow generated by exhaling causes an output voltage of the opposite polarity. In any event, it is preferred that the sensor 40 be capable of detecting both inspiration and expiration.

In addition to the preferred flow sensor, it should be understood that other types of sensors may be utilized to detect variations in respiration, preferably inhalation and exhalation. Those skilled in the art will recognize that pressure transducers, thermistors or infrared detectors may all be used to sense inhalation. In one example, a pressure transducer with the appropriate sensitivity, such as a solid-state piezoresistive, capacitive or electromechanical device, could be used to generate an electrical signal in response to the breathing cycle. In another example, thermistors could be used to detect changes in airflow due to respiration. If the thermistor was sufficiently sensitive, one may be able to ascertain the onset of inhalation by monitoring the temperature of a thermistor (or thermocouple) placed near the nostril. A flow measurement may also be possible with the use of two thermistors in an anemometer configuration. Infrared detectors, such as single element bolometers, could be used as well if they possess the speed and accuracy to distinguish variations in respiration.

The respiration sensor 40 provides a signal to the respiration sensor/valve controller 42 which compares the signal to a predetermined reference level. The respiration sensor/valve controller 42 identifies the onset of inhalation by triggering when the sensor signal reaches the predetermined reference level. The respiration sensor/valve controller 42 then provides a signal to position the spool of valve 26 so oxygen flows from supply 20 to patient 16 via supplemental oxygen delivery device 18. The spool of the valve 26 remains in this position for a period of time, the "dose time" (D), as specified by the system controller 10. In this manner, a dose of oxygen of duration D can be provided when the patient is inhaling.

One preferred valve 26 of the embodiment of Figure 2 is a three-way, two-position, solenoid-actuated spool valve having three ports 26a, 26b, 26c. Common port 26a is connected to the in vivo respiratory system of the patient 16 by the supplemental oxygen delivery device 18. Normally closed port 26b is connected to the oxygen source 20 and normally open port 26c is connected to respiration sensor 40 (with the other end of the preferred respiration sensor left open to atmosphere).

One preferred valve 26 is manufactured by The Lee Company, of Westbrook, Connecticut, Model HDI LHDA0523111H.

When oxygen is not being supplied to the patient 16, the spool of the valve 26 is positioned such that common port 26a and normally open port 26c are connected so that the respiration sensor 40, supplemental oxygen delivery device 18, and patient 16 are in fluid communication, corresponding to the OFF position of the valve 26. This allows the respiratory effort of the patient 16 to be detected by the respiration sensor 40, through the monitoring of the flow generated in the supplemental oxygen delivery device 18 by inspiratory and expiratory efforts.

To supply oxygen to the patient 16, the spool of the valve 26 is moved so as to connect common port 26a and normally closed port 26b, corresponding to the ON position of the valve 26. This, in turn, allows for flow of respiratory oxygen to the patient 16 from supply 20 through the valve 26 and the supplemental oxygen delivery device 18.

The ON period for the valve 26, corresponding to the dosage period as discussed below, is preferably shorter than the inhalation period for the patient. As a result, the patient may often be inhaling after the valve 26 is OFF (i.e., closed). To reduce or prevent multiple openings of the valve 26 during a single inhalation, it is preferred that the valve 26 remain closed until the sensor 40 detects the onset of exhalation. Once exhalation is detected based on the sensor 40, the system can then resume monitoring for the onset of inhalation, whereupon the cycle is repeated.

Because the preferred valve 26 is a 3-port valve, there is a short period after opening or closing the valve 26, (the "bounce period") where the sensor output voltage spikes or bounces due to oxygen leaking from the normally closed port 26b to the normally open port 26c while the valve spool is still moving. Once the valve 26 is fully ON or OFF and the valve spool has stopped moving, the bounce signal disappears. It is preferred that monitoring of the respiration sensor 40 be adjusted to avoid false readings due to the bounce signal after turning the valve 26 ON or OFF. This adjustment can take the form of a delay in monitoring the signal provided by the

sensor 40 after moving the valve 26 between the ON and OFF positions until the bounce signal has passed.

In some systems, the bounce signal may be monitored and used advantageously. The bounce signal (whether generated during ON or OFF movement of the valve spool) may be used to detect the presence of oxygen at the supply 20. No bounce signal may indicate that no oxygen is present because of the lack of pressurized oxygen at normally closed port 26b. In the preferred embodiment, the bounce signal generated by turning the valve 26 to the OFF position (i.e., closing port 26b) is used for this check because that bounce signal is typically larger and longer in duration than the bounce signal generated by turning the valve 26 to the ON position (i.e., opening port 26b).

Another advantage of the 3-port valve 26 is that sensor's zero-flow offset voltage can be checked while the valve 26 is in the ON position. The measured sensor offset voltage signal (Vo) can be used to generate a correction for drift in the sensor offset voltage. After the valve 26 has been ON longer than the valve-ON bounce period, the signal from the respiration sensor 40 can be read and recorded for use in, e.g., a software-generated correction for zero-flow sensor offset voltage. This sensor offset voltage signal is obtained from the respiration sensor 40 when the valve 26 is ON because no flow is to be expected through the respiration sensor 40 under those conditions (port 26c is closed). In addition, if this offset reading is greater (in absolute value) than a predefined upper limit (VoMAX), this can be used to indicate either sensor 40 or valve 26 failure; e.g., the sensor 40 has drifted too far out of specification, the valve 26 is leaking, the valve 26 is stuck in the OFF position, etc.

The demand delivery module 12 described above is a subsystem that communicates to and receives communication from system controller 10. In the described methods, it receives continually updated values of the dose time D. It will be understood, however, that those skilled in the art could design a demand delivery module 12 which is more or less dependent on the system controller 10 than is

described in this embodiment. For example, it may be desirable to construct a system where respiration sensor 40 provides a signal directly to the system controller 10 with no separate respiration sensor/valve controller 42 being provided. The controller 10 would then provide a control signal to valve 26 directly as well as perform the other operations that are described as being performed by the respiration sensor/valve controller 42.

Moreover, it should be understood that alternative designs for the connections of the valve 26, respiration sensor 40, oxygen source 20, and patient 16 may be envisioned by the those skilled in the art. It would be possible to design a system in which an in-line flow sensor and/or three-port, two-way valve are not required. For example, the designs may involve a plurality of valves and sensors. It should be understood that the methods and systems of the described device operate independently from the specific configuration of hardware used for sensing variations in respiration and the specific valve configuration used to control the flow of oxygen.

Although the demand delivery module 12 described above is used to control delivery of supplemental oxygen to a patient from the source 20, the demand delivery module 12 and the methods of operating it as described above could find wider application. For example, they could be used in connection with critical care systems in which FiO_2 is to be controlled via the use of masks or other delivery devices used in connection with, e.g., respirators, ventilators, BIPAP (Bilevel Positive Airway Pressure) systems, etc. As a result, the demand delivery module and methods of operating it are not to be limited to use in connection with systems and methods of delivering supplemental oxygen as part of a sub-acute care regime.

As long as the data stream from the blood oxygen content sensor 14 is valid (as described in detail below), the controller 10 can use the data to control delivery of oxygen to the patient. The feedback control can be implemented as a portion of software code contained in the controller 10; however, it could alternatively be a hard-wired controller or combination of hardware and software in other embodiments.

There exist a variety of control methods that are of utility in the present method and invention. The goal of any control method is stable operation of the controlled system about a setpoint or desired value. In the preferred embodiment, the desired value is a blood oxygen saturation (SpO_2) of 90%. One control algorithm, the ON/OFF method, is diagrammed in Figure 3a. This diagram assumes that the data generated by the blood oxygen content sensor is valid (validity and invalidity of that data is discussed in more detail below).

The system measures the patient's blood oxygen content level 100. With that information, a decision 102 is made. When the measured blood oxygen content level is not below the desired value no oxygen is delivered 104. When the measured blood oxygen content level is below the desired value, oxygen is delivered 106. For example, when the measured blood oxygen content level is not below the desired value, controller 10 sets a dose time of zero (D=0), thereby preventing the delivery of supplemental oxygen. Alternatively, the system may otherwise restrict the flow of oxygen by, e.g., reducing its flow to a very low value in an attempt to conserve the supplemental oxygen source. The reduction in flow can be accomplished using a variable flow valve or by introducing a flow restrictor into the system between the source 20 and the patient 16. When the measured blood oxygen content falls below the desired value, controller 10 delivers supplemental oxygen to the patient 16 by, e.g., setting a non-zero value (D>0) for the dose time or otherwise increasing the flow of oxygen to the patient.

As long as the measured blood oxygen content level remains below the desired value, the system provides oxygen when the patient is inhaling. In one relatively simple implementation, the "ON" dose time D could be very long. Preferably, however, the dose time is equal to or shorter than a typical inhalation period, in which case one or more pulses of duration D of oxygen are delivered during inhalation. This ON/OFF control approach is analogous to the operation of a furnace using a mercury switch thermostat, i.e., oxygen delivery is either ON or OFF.

The feedback control algorithm may alternatively use a Proportional-Integral-Derivative (PID) loop as illustrated in Figure 3b. Other embodiments could use algorithms based on fuzzy logic, look-up tables, P or PI loops or increment/decrement methods (oxygen delivery that increases or decreases in a preprogrammed fashion relative to setpoint and/or trend). The PID algorithm is fundamentally different from the simple ON/OFF control algorithm in that it uses both the current value of the blood oxygen content and also trend information to determine whether the patient needs supplemental oxygen and, if so, how much oxygen should be delivered when the patient is inhaling. Because of the use of trend information, a system controlled with a PID loop will, at times, deliver oxygen to the patient even if their blood oxygen content is above the desired value; or, at other times, it may not deliver oxygen even if they are below the desired value. An example of when this might occur is when the patient's blood oxygen content was above the desired value, but was also dropping very quickly. In this case, the PID loop would start oxygen delivery before the blood oxygen content actually fell below the desired value. (The ON/OFF method would not start oxygen delivery until after the blood oxygen content was below the desired value). This may allow a PID control method to more effectively reduce the fluctuations of the blood oxygen content about the desired value.

A simplified flow diagram of one such PID control system is illustrated in Figure 3b where the data stream of the measured blood oxygen content level sensor is assumed to be valid (validity/invalidity of that data is discussed in more detail below). The system measures the patient's blood oxygen content level 110. The current information is compared with earlier data 112 to determine how much oxygen (i.e., a variable dose), based on the parameters of the PID loop 114, should be delivered to the patient 116. In some instances, the parameters of the PID loop indicate that no oxygen is to be delivered 118, and in other instances some variable dose of oxygen will be delivered based on the parameters of the PID loop.

The preferred systems for implementing the methods of the present invention use a digital controller. As a result, discretization of the following continuous-time PID control equation must be performed:

$$D(t) = K_p*[e(t) + (1/T_i)*\int e(t')dt' + (T_d)*de/dt] \quad (1)$$

where D(t) is the oxygen dose time at time *t*, K_p is the loop proportional gain, T_i is the integral time, T_d is the derivative time, and where the integral is integrated over the range of from zero to *t*. The preferred embodiment utilizes a first order discretization of the continuous time PID equation. This can be seen in Equation 2,

$$D(t_n) = D(t_{n-1}) + A_0e(t_n) + A_1e(t_{n-1}) + A_2e(t_{n-2}) \quad (2)$$

where $D(t_n)$ is the control signal (oxygen dose time) generated for time period t_n, $e(t_n)$ is the difference between the desired level of blood oxygen saturation (the setpoint) and the measured level at time t_n. The coefficients, A_0, A_1, and A_2 are given by Equations 3-5 below:

$$A_0 = K_p*(1+ t_n/t_i + t_d/t_n) \quad (3)$$

$$A_1 = -K_p*(1+ 2*t_d/t_n) \quad (4)$$

$$A_2 = K_p*(t_d/t_n) \quad (5)$$

where K_p is the loop proportional gain, t_i is the integral time, t_d is the derivative time and t_n is the period of the measurement (one second if using the preferred oximeter).

As mentioned, the quantity $e(t_n)$ is the difference between the SpO_2 value at time t_n and the desired value. In one embodiment, a fixed setpoint of SpO_2=90% is used for the desired value. The control algorithm will specify doses of oxygen in order to maintain the blood oxygen saturation at this level. It is thought that this saturation level may provide the necessary correction to the patient's hypoxemia, while at the same time conserving the greatest amount of oxygen. It should be

apparent to those skilled in the art that the desired value (setpoint) can be changed to achieve different therapeutic and economic goals.

Moreover, a system that uses additional physiological parameters, such as pulse rate or respiratory rate, in addition to blood oxygen content as determined by the oxygen sensor to determine a target blood oxygen level (setpoint) that changes on a rolling basis could also be implemented. For example, one may use the heart rate to monitor the patient's activity level and therefore anticipate increased or decreased need of oxygen and adjust the setpoint accordingly. Such schemes would be seeking to ameliorate the possible increased/decreased hypoxemia caused by a change in physical activity level. Such changes to the setpoint should be considered to be within the spirit and scope of the present invention.

Referring now to Equations 3-5 above, the transfer function coefficients A_0, A_1 and A_2 are determined by the settings of loop proportional gain K_p, the integral time t_i, the derivative time t_d and the time between data points t_n. The determination of these values will typically be accomplished through clinical monitoring of COPD patients while the system is in use. The specific values of these loop parameters will depend on design goals such as loop stability, overshoot, time-to-achieve-control, and accuracy. Methods for obtaining values which provide for effective operation of the control loop will be known to those skilled in the art.

In one method, the control signal $D(t_n)$ is the dose time needed to maintain the blood oxygen level at the desired value. The dose time signal is provided by controller 10 to respiration sensor/valve controller 42. It is the duration of time that valve 26 will be held in the ON or open position which permits oxygen to pass from supply 20 to patient 16 (via the supplemental oxygen delivery device 18 illustrated in Figures 1 and 2). A dose of oxygen of duration $D(t_n)$ is provided during inhalation (as indicated by respiration sensor 40 and sensor and valve controller 42, described previously).

It should be understood that other methods besides varying the dose time could also be employed to control the patient's blood oxygen content. For example,

a system which includes a variable-flow valve (as opposed to the preferred open/closed valve) could be constructed. In such a system, the controller 10 could specify the oxygen flow level. The specified flow could, in turn, be provided for a fixed period of time at the onset of each breath, or continuously. During those times in which the patient does not require supplemental oxygen and/or is not inhaling, the flow could be restricted to a low level or to zero followed by periods in which the flow is higher (when the patient is in need of supplement oxygen and is inhaling).

Alternately, the blood oxygen content could be controlled by providing a dose of oxygen on one or more sequential breaths and then delivering no oxygen on one or more subsequent breaths. In this method, the control parameter could be described as the number of breaths during which oxygen is or is not delivered. It should be understood that those skilled in the art could construct a control scheme which uses any of these alternate methods or a combination of these methods.

The controller 10 also may include a minimum limit (Dmin) for the dose time. If the dose time $D(t_n)$, as determined by Equation 2, is less than Dmin, a dose time of Dmin will be used instead. In one embodiment, Dmin will be zero. The dose time $D(t_n)$ determined by Equation 2 will, at times, be negative. This will primarily occur when the patient's blood oxygen content is greater than the desired value. Since a negative dose time is not physically meaningful, the controller will instead substitute a dose time of Dmin. Of course, Dmin could also be greater than zero.

Similarly, in one embodiment the controller 10 would also have a maximum limit (Dmax). If the dose time $D(t_n)$, as determined by Equation 2, is greater than Dmax, a dose time of Dmax is used instead. In one embodiment, Dmax is equal to twice the default dose (described in detail below). This prevents the application of excessive amounts of oxygen and thus minimizes the patient's risk of hypercapnia (carbon-dioxide retention). Those skilled in the art will appreciate that other values of Dmax could also be used.

In another embodiment, the controller 10 could include an "anti wind-up" provision. Because the dose time may have minimum and maximum limits (Dmin

and Dmax, described above), it may be advantageous to include an anti wind-up provision to prevent the integral portion of the PID-calculated dose time from getting too large or too small. One way this could be implemented is as follows: If the previous PID-calculated dose time $D(t_{n-1})$ (from Equations 2-7) is less than Dmin or greater than Dmax, the integral term from Equation 3 is deleted (i.e., Equation 3 is replaced with Equation 3a, below):

$$A_0 = K_p*(1+t_d/t_n) \qquad (3a)$$

In systems and methods according to the present invention, the ability to respond to periods of invalid or bad data in the blood oxygen content measurements is preferably provided. In the preferred methods and systems, the delivery of oxygen moves from the closed loop control described herein to open loop control based on the criteria described herein (i.e., default values, interpolated data, etc.) and back to closed loop control when the blood oxygen measurements are again valid. Figure 4 illustrates these concepts. As shown, the system obtains a measured blood oxygen content level 120. A decision is then made as to whether the measured blood oxygen content level data is valid or invalid 122. The system may determine whether the measured blood oxygen content level data is invalid on a point-by-point basis or it may determine whether the data stream (including a plurality of data points) is invalid as discussed below. Regardless, a decision will be made as to whether the measured blood oxygen content level data is valid. If the measured blood oxygen content level data is invalid, the system will deliver a default amount of oxygen to the patient 124. If the measured blood oxygen content level data is valid, the system will deliver oxygen to the patient 126 according to the appropriate control algorithm (ON/OFF, PID loop, etc.).

In other words, the methods/systems according to the present invention will determine when the blood oxygen content data is invalid, deliver a default amount of oxygen during periods of invalid data, and then resume delivery of supplemental

oxygen based on blood oxygen content when that data is again valid. The ability of the systems and methods of the present invention to move from closed to open and back to closed loop control provides a robust system that can operate with a minimum of supervision from medical personnel. Those qualities are essential in any system designed for residential or ambulatory use by sub-acute patients.

The following description illustrates some preferred methods for accomplishing these features, but it should be understood that in its essence the present invention provides for that movement from closed loop control to open loop control and back to closed loop control based on the presence of valid or invalid blood oxygen content measurements.

In one embodiment, before the measured blood oxygen saturation reading ($Sp0_2$) is used for determining the dose time D of oxygen to be delivered to the patient 16 from the oxygen source 20, various error handling and artifact detection procedures are followed to prevent erroneous over- or under-dosing of oxygen to the patient. In one embodiment of the present invention, the error flags provided by the oxygen sensor 14 in the serial data stream are combined with a numerical analysis of the $Sp0_2$ data to create an artifact detection and handling scheme.

The serial data stream of the preferred pulse oximeter 14 provides one data point per second. Each data point includes three bytes of information, as follows:

1st byte = Status	Bit 7 = Always set to "1"
	Bit 6 = Sensor disconnected, set if true
	Bit 5 = out of track, set if true
	Bit 4 = low perfusion, set if true
	Bit 3 = marginal perfusion, set if true
	Bit 2 = bad pulse, set if true
	Bit 1 = heart rate bit 8
	Bit 0 = heart rate bit 7

2nd byte = Heart Rate	(511 = bad data) Bit "7" is always set to "0" Heart Rate Data = Bits 0 - 6 Plus bits 0 & 1 of status byte to provide 9 bits of resolution
3rd byte = SpO_2	(127 = bad data)

The first byte of the data point may include error flags for some problems associated with pulse oximetry. These flags are examined for the occurrence of a disconnected sensor, low or marginal perfusion, out of track oximeter and bad pulse. If any of these flags are set, the accompanying SpO_2 and heart rate data is considered bad. If the data point is determined to be bad, a timer (Timer1) is started by the controller 10 (unless it is already running based on an earlier bad data point) which then waits for the next data point. The function of Timer1 is to track the cumulative time over which consecutive bad data points are being received. Timer1 is stopped and reset to zero each time a valid or good data point is received.

If, however, none of the flags is set, a second error check may be performed using a statistical analysis of the data. The new data point is compared to a mean value of previous data points which represents the patient's current blood oxygen content. The details of the calculation of this mean value are described below. The current data point is subtracted from the mean value to generate a difference, ΔSpO_2 in %. (For the data-validity analysis below, if ΔSpO_2 is less than zero, its absolute value is used.)

If the absolute value of $\Delta SpO_2 > 4\%$ and Timer1 equals zero (i.e., the last data point was valid), then the current data point is determined to be invalid. Since the time between data points in the serial data stream will be about one second, a change larger than 4 percent in the SpO_2 in such a short time would be physiologically impossible. If the data point is determined to be invalid using this

procedure, the data is ignored, Timer1 is started and controller 10 waits for the next data point.

If, however, the absolute value of $\Delta SpO_2 > 4\%$ and Timer1 does not equal zero, then additional evaluation may be performed. The observed rate of oxygen desaturation in humans can approach 20%/minute or about 3% every 10 seconds. If Timer1 is less than 10 seconds and the absolute value of $\Delta SpO_2 > 4\%$, then the data is considered to be invalid. If Timer1 is greater than 10 seconds, but less than 20 seconds then the acceptance criteria is absolute value of ΔSpO_2 less than 8% for the data to be valid. If Timer1 is greater than 20 seconds, but less than 30 seconds then the acceptance criteria is absolute value of ΔSpO_2 less than 12%. If Timer1 is greater than 30 seconds, then oxygen is delivered using the default method which is described in detail below. It should, of course, be understood that, in the above analysis, the specific values of 4%, 8%, and 12%, and the specific times of 10, 20 and 30 seconds could be replaced with different values.

Some alternate criteria for identifying when individual data points are invalid or bad could include, but are not limited to, identifying an invalid data point when: (a) the SpO_2 value is outside upper and/or lower limits (e.g., a lower limit of about 70% and/or an upper limit of about 98%); or (b) the heart rate is outside upper and/or lower limits (e.g., a lower limit of about 40 beats per minute and/or an upper limit of about 200 beats per minute).

If the data point passes all the tests, Timer1 is stopped and set to zero (if necessary) and the new mean value of blood oxygen content is calculated with the most recent data point. The new mean value is then compared to the setpoint and a dose time D is calculated as detailed above in Equations 2-5.

In one embodiment, an exponentially-weighted arithmetic mean of the previous data points is used to represent the current blood oxygen content. The new mean is calculated as follows:

$$\text{new mean} = (\text{current data point}) * W1 + (\text{previous mean}) * W2 \qquad (6)$$

where

$$W1 = 1 - \exp(-\Delta t/T) \qquad W2 = \exp(-\Delta t/T). \qquad (7)$$

Here Δt is the time between data points (one second using the preferred oximeter), and T is a parameter which represents an appropriate time scale for the averaging. If an appropriate value of T is chosen, the exponentially-weighted mean will smooth out normal point-to-point "noise" fluctuations in the pulse oximeter data without masking the real trends related to the patient's blood oxygen content. (A typical value would be T = 10 seconds, although other values could be used.)

Other methods could also be used to determine a mean value that is representative of the patient's current blood oxygen content. For example, a harmonic, or geometric mean might be used. (Descriptions of these types of means can be found in "Standard Mathematical Tables" by CRC Press, 24th edition, pages 470-471.) Alternately, a "running" mean might be used. In this method, the mean of a fixed, predetermined number of the most-recent data points could be used. For example, with the preferred pulse oximeter which delivers one data point per second, one could average the preceding 10 data points, thus calculating a mean which represents the patient's blood oxygen content for the previous 10 seconds.

In one embodiment, the dose time D of oxygen that is delivered to the user may depend on the validity of the data stream from the oxygen sensor. If the time over which the consecutive invalid or bad data points are received, as indicated by Timer1, exceeds a predetermined, physiologically-relevant time scale for patient desaturation (referred to as Desattime), alternative, "default" oxygen delivery procedures are employed. In one embodiment Desattime is equal to 30 seconds. The default assumption is that a patient is always in need of oxygen, unless the blood oxygen content sensor positively indicates that they are not.

If the current oxygen sensor data point is invalid, but Timer1 is less than Desattime, the oxygen dose time D may remain unchanged from its current value. The system will provide a dose of this duration at the onset of inhalation. The process of gathering and evaluating blood oxygen saturation data then continues. Prior to the onset of invalid data, the system was either administering oxygen to correct a deficiency or the patient was in no need of oxygen. Thus, in this embodiment it is assumed that the patient's oxygen needs have not changed during this short time of invalid data and the status quo is maintained. If the patient was receiving no oxygen prior to the invalid data (e.g., dose time D=0), the system will not administer any oxygen. If, however, the patient was receiving oxygen (e.g., D>0), the system will typically continue to administer the same dose by responding to inhalation as described above. This will preferably continue until either a valid data point is received and a reevaluation can be made of the patient's condition or Timer1 exceeds Desattime.

If the oxygen sensor data points continue to be invalid and Timer1 exceeds Desattime, then the device will default to another oxygen delivery method. In the default method, the controller 10 will default to administering a prescription-equivalent dose of oxygen to the patient 16 from the oxygen source 20 via the demand delivery module 12. This default dose of oxygen could take many forms: In one embodiment, the default could be a continuous flow of oxygen. To implement this, the system could output a very large dose time to hold valve 26 in the ON position which allows oxygen to flow from source 20 to patient 16. Alternately, in the preferred embodiment, the default mode would provide a short dose of oxygen (of duration D=Ddefault) at the onset of inhalation for almost every breath. In this preferred embodiment, Ddefault would be shorter than a typical inhalation period, in which case the system would provide pulses of duration Ddefault synchronized with each inhalation (demand mode). This will continue until such time as the blood oxygen content data is valid and closed-loop control over oxygen delivery can start anew.

It is possible to envision additional alternate methods of default flow. In one such alternate embodiment, the valve does not necessarily open with each and every breath. It should be understood that these alternate methods of implementing a default flow still fall within the scope of the present invention. The object of the default method is to provide a total flow of oxygen during this period of default operation that is no less than the physiological equivalent amount that is prescribed to the patient by the physician. (Physiological equivalence meaning the amount dispensed by other demand delivery devices to provide adequate oxygen therapy.) It should be understood that the notion of physiological equivalence as regards demand delivery devices will change over time as their effects on the physiology of COPD patients is better understood by the medical community. Current practice indicates that 35 ml delivered every other breath at the beginning of inhalation is equivalent to a continuous flow of 2 liters/minute of pure oxygen.

In one embodiment of the invention, the duration of the default dose (Ddefault) may be set by the patient's respiratory therapist using a hardware switch on the user interface 32 that is not accessible to the patient. Other techniques of setting the pulse width may be possible, such as a remote controllers, push buttons, etc.

Also, in one embodiment, if Timer1 exceeds Desattime, then the previous mean value of the blood oxygen saturation is reset and data acquisition starts anew. In this way, it is assumed that the old SpO_2 information is no longer valid for the patient's current physical state and that to properly administer oxygen a more current measure of the blood oxygen level is needed. Thus, by using Timer1, a period of invalid data that exceeds Desattime will always lead to the administration of oxygen to the patient. This will correct any undetected desaturation events. Moreover, the controller 10 will always use the most current, valid information regarding the patient's blood oxygen level.

It should also be understood that other methods for recognizing and handling erroneous data points from the oxygen sensor could be devised. Those skilled in the

art could create different algorithms for handling invalid data points, such as replacement of invalid data points with interpolated values based on the recent trend in the blood oxygen saturation. Alternative methods of identifying and rejecting invalid data points should be considered to be within the scope of the present method and system.

Another method for determining whether the oxygen sensor data is valid or invalid can be based on the data stream (a plurality of data points) rather than the individual data points. For example, instead of tracking the time since the most recent valid data point or points, the system could instead determine if the data stream is valid or invalid by comparing the number of valid data points in a "look-back" window (for example, the 60 to 100 most recent data points) to a preset minimum threshold. If the number of valid data points in the look-back period is greater than or equal to the specified minimum, the data stream is considered to be valid and the calculated dose is delivered; if the number of valid data points is less than the minimum, the default dose is delivered.

Those skilled in the art will understand that a wide range of possibilities for oxygen delivery in default mode beyond those that have been described here could be used. Although they are not described in detail herein, they should be considered as falling within the scope of the methods according to the present invention.

If invalid data is a problem, the controller 10 may be used to notify the patient of a problem with the pulse oximetry via the user interface 32 and/or alarm 38. This notification may take the form of a warning light, readout, buzzer or some combination of these. Those skilled in the art may also conceive of other methods of warning the user that are not detailed herein. After the warnings have been issued and default demand flow mode entered, the controller 10 resumes monitoring the output of the oxygen sensor for valid data.

Along with monitoring the breathing cycle for oxygen delivery, the invention makes provision for the detection of apnea, the cessation of breathing for a prolonged period of time. Timer2 starts each time an inhalation is detected. If the

elapsed time between breaths is greater than a predetermined time, e.g., 15 seconds, as determined by Timer2, then the alarm circuit 38 is activated by the controller 10 to signal the patient of a possible apneic event. These alarms preferably stop sounding upon detection of the next inhalation.

Other alarms and indicators that can be included in the systems and methods of the present invention include hypoxia alarms, high respiration rate alarms, high/low pulse rate alarms, and patient monitoring indicators. These alarms and/or indicators can be used to warn the patient that their supplemental oxygen equipment is not operating properly, they are not using it properly, or they are having other problems and need to seek medical treatment.

In the case of an hypoxia alarm, the patient could be provided with a visible and/or audible alert when their blood oxygen saturation level has been below a healthy level for a period of time - even though they have been using the above-described device. This condition could be caused, e.g., by a malfunctioning of the supplemental oxygen equipment or a worsening of the patient's respiratory condition. In normal operation of the preferred embodiment as described above, the device would increase the dose time D(t) in response to the patient's hypoxia, up to a preset upper-limit dose time Dmax. It is possible that the patient's condition could have worsened so much so that even this maximum dose is not sufficient to keep their blood oxygen saturation at a healthy level. It would be advantageous to alert the patient to this condition so they may seek appropriate medical attention. This could enable earlier detection and treatment of potentially dangerous and costly health conditions.

The hypoxia alarm could be implemented in software, hardware, or in a combination of software and hardware. In the methods described above, the controller 10 may already calculate a mean value of blood oxygen content from the valid blood oxygen saturation data points. In the preferred embodiment, the mean value that is already calculated is an exponentially-weighted arithmetic mean with a typical time constant T=10 seconds. This mean represents the average blood oxygen

saturation for the previous 10 seconds. For the hypoxia alarm, a second mean value of blood oxygen saturation, for a longer period (e.g.. T=1 hour) could be calculated in an analogous manner. In the preferred embodiment, this hypoxia alarm mean would also be an exponentially-weighted mean because it eliminates the need to store each of the many data points that would be collected over the longer period, thereby decreasing the memory requirements.

It should be understood, however, that other methods of calculating a mean as discussed above could also be used. When the second mean falls below a preset limit representing the lower limit for healthy blood oxygen levels (e.g., 88%), controller 10 could alert the patient via alarm circuit 38. In the preferred embodiment, the time period for the second mean is 1 hour, and the lower limit for blood oxygen saturation is 88%; however, it should be clear that other values could be used for these parameters.

In the case of a high respiration rate alarm, the patient could be provided with a visible and/or audible alert when their respiration rate has been above a healthy level for a period of time. Some patients with respiratory diseases will compensate for an impaired respiratory system by maintaining a higher than normal breathing rate. These patients can sometimes maintain a healthy blood oxygen saturation, but over the long term, the increased respiration rate is also detrimental to their health. The onset of a period of increased respiration rate could be caused by a malfunctioning of the supplemental oxygen equipment or a worsening of the patient's respiratory condition.

In normal operation of the preferred embodiment as described above, the device increases the dose time D(t) in response to the patient's hypoxia. It is possible that the patient's condition could have worsened, but the patient is compensating by breathing at a higher rate. As with hypoxia, it would be advantageous to alert the patient to this condition so they may seek appropriate medical attention.

This alarm could be implemented in software, hardware, or in a combination of software and hardware. The system described above already measures the elapsed

time between each breath via Timer2. For the high-respiration rate alarm, a mean value of the elapsed time between each breath could be calculated in a manner analogous to the mean blood oxygen levels. In the preferred embodiment, this mean would also be an exponentially-weighted mean. It should be understood, however, that other methods of calculating a mean as described above could also be used. When the mean elapsed time between breaths falls below a preset limit corresponding to the upper limit for healthy respiration rates (e.g., minimum elapsed time of two seconds, corresponding to a breathing rate of 30 breaths per minute), the system could alert the patient via controller 10 and alarm circuit 38. In the preferred embodiment, the time period for calculating the mean is 1 hour, and the lower limit for elapsed time between breaths is 2 seconds (30 breaths per minute); however, it should be clear that other values could be used for these parameters.

In the case of a high/low pulse rate alarm, a visible and/or audible alert could be provided to the patient when their pulse rate has been above or below healthy levels for a period of time. Excessively high or low pulse rates could be an important indication that the patient needs medical treatment. It would be advantageous to alert the patient to these conditions so they may seek appropriate medical attention.

In the preferred embodiment, these alarms would be implemented in software, hardware, or in a combination of software and hardware. The preferred oxygen sensor typically provides pulse rate data (in addition to blood oxygen data). A mean pulse rate could be calculated in a manner analogous to the calculation of other means, described above. As with the other alarms, in the preferred embodiment, this mean would also be an exponentially-weighted mean or, alternatively, other means or averages could be used.

When the mean pulse rate falls above or below preset limits (e.g., less than 40 or above 180 beats per minute), the system could alert the patient via alarm circuit 38. In the preferred embodiment, the time period for the mean is 20 minutes, the lower limit for pulse rate is 40 beats per minute, and the upper limit for pulse rate is

180 beats per minute; however, it should be clear that other values could be used for these parameters.

Among the indicators that could be provided include various patient and equipment monitoring functions. In the preferred embodiment, these indicators could be implemented in software, hardware, or in a combination of software and hardware. The information provided by these indicators could be useful to the patients, respiratory therapists, physicians, etc. Some examples of indicators are described below.

One indicator that could be useful is an "ON-time" indicator. An important factor in treating patients that require supplemental oxygen is monitoring their compliance with their oxygen prescription. Some patients will not use their oxygen equipment as much as they should. Medical studies have shown that most patients must use their supplemental oxygen equipment at least 18 hours per day in order to receive significant benefits from it. The ON-time parameter would indicate the total amount of time that the device has been powered ON (analogous to the "hour meter" found on most oxygen concentrators), thus giving an indication of the total time the equipment was used since the ON-time parameter was last reset to zero. In the preferred embodiment, a timer would be started by controller 10 each time the unit was turned ON. When timer reached a value of, e.g., one minute, controller 10 would increment a non-volatile memory location and reset and restart the timer. In this manner, a memory location associated with the ON-time timer would count the number of minutes the apparatus had been powered ON. The memory location associated with the ON-time timer would preferably be non-volatile and, as a result, the total minute count would be retained while the unit was powered OFF. When powered ON again, counting would resume from the previously accumulated value. In the preferred embodiment, the ON-time timer could be accessed and reset via the user interface 32.

It may also be useful to track the total number of times each alarm condition has occurred. In the preferred embodiment, a separate non-volatile memory location

would be used to count the number of times each alarm condition had occurred. Each time an alarm condition occurred, the associated memory location would be incremented. In addition to the three alarms described above, the preferred embodiment could also count the number of apnea alarms. The various alarm-count parameters could be accessed and reset, e.g., via the user interface 32.

It may also be useful to keep track of the total amount of time the unit was in "default" mode as described above. In a manner similar to tracking ON-time, the default time monitor would preferably consist of a non-volatile memory location that would be incremented each time the timer reached one minute and the unit was in the default mode. In a similar manner, a feedback-control-time parameter could be calculated (although this parameter may be more easily obtained by subtracting the default time from the ON-time). As with the other monitored parameters, default time would preferably be accessed and reset via the user interface 32.

It may also be useful to keep track of the total number of times the apparatus entered the "default" mode. In the preferred embodiment, a separate non-volatile memory location would be used to count the number of times the default delivery condition had occurred. Each time the apparatus entered the default delivery mode, the associated memory location would be incremented. The default count parameter would preferably be accessed and reset via the user interface 32.

It may also be useful to keep track of the total amount of time the patient was hypoxic (e.g., SpO_2 <88%). In a manner similar to tracking the ON-time, the hypoxic-time monitor would consist of a non-volatile memory location that would be incremented each time the timer reached one minute and the patient was hypoxic (and the SpO_2 data was deemed valid). As with the other monitored parameters, hypoxic-time could be accessed and reset via the user interface 32.

It may also be useful to keep track of the average duration of the pulses of oxygen that are provided at each inhalation (i.e., the average dose time). The average-dose-time parameter could provide a useful indication of the amount of supplemental oxygen that was required to keep the patient's blood properly

oxygenated. Trends in this parameter could be useful for tracking the overall efficiency of the patient's respiratory condition. For example, a measurable increase in the average-dose-time (i.e., an increase in the amount of supplemental oxygen needed) could indicated a worsening of the patient's condition, and thus provide an early warning allowing the patient to seek medical attention before their condition required a costly hospitalization.

In the preferred embodiment, two nonvolatile memory locations would be used to calculate average-dose-time: a counter and an accumulator. Each time, e.g., an inhalation was sensed, the current dose time (as indicated by controller 10) would be added to accumulator and the counter would be incremented. The average-dose-time could then be calculated by dividing the accumulator value by the counter value. As with the other monitored parameters, average-dose-time could be accessed and reset via the user interface 32.

In addition to those parameters specifically recited herein, other useful parameters may also be generated. For example, average SpO_2 (the patient's average blood oxygen saturation); average respiration rate; average heart rate; etc. Monitoring of these parameters could also be implemented in software, hardware, or in a combination of software and hardware.

Various methods and systems for conserving supplemental oxygen delivery to a sub-acute patient based on continuous blood oxygen content measurements and inhalation have been described above. Many changes, alterations and variations of the subject invention will become apparent to those skilled in the art after consideration of this specification and the accompanying figures and diagrams of the preferred embodiments. For example, the values chosen for, e.g., ΔSpO_2, Timer1, Timer2, etc., are intended to be exemplary of some preferred values and should not limit the scope of the invention unless the values are explicitly recited in the claims. All such changes, modifications, variations, etc. are deemed to be covered by the claims which follow.

What is claimed is:

1. A method of controlling supplemental oxygen delivery during sub-acute care comprising:

continuously measuring blood oxygen content of a patient to obtain a measured blood oxygen content level;

delivering supplemental oxygen from an oxygen source to the patient when the patient is inhaling if the measured blood oxygen content level is below a desired value; and

restricting the delivery of supplemental oxygen if the measured blood oxygen content level of the patient is above the desired value.

2. A method according to claim 1, wherein the supplemental oxygen is delivered through a supplemental oxygen delivery device.

3. A method according to claim 2, wherein the supplemental oxygen delivery device comprises a nasal cannula.

4. A method according to claim 1, wherein restricting the delivery of supplemental oxygen comprises preventing the delivery of supplemental oxygen.

5. A method according to claim 1, further comprising sensing variations in respiration of the patient to determine when the patient is inhaling.

6. A method according to claim 5, wherein the sensing comprises sensing when the patient is inhaling.

7. A method according to claim 5, wherein the sensing is performed using a flow sensor.

8. A method according to claim 7, wherein the flow sensor comprises a bidirectional flow sensor.

9. A method according to claim 1, wherein the method is performed in a residential setting.

10. A method according to claim 1, wherein the desired value for the measured blood oxygen content level is about 90%.

11. A method according to claim 1, wherein the measured blood oxygen content level is obtained using a pulse oximeter.

12. A method according to claim 1, further comprising:

determining if the measured blood oxygen content level is invalid; and

delivering a default amount of supplemental oxygen to the patient when the measured blood oxygen content level is invalid.

13. A method of controlling supplemental oxygen delivery for sub-acute care comprising:

continuously measuring blood oxygen content of a patient to obtain a measured blood oxygen content level;

sensing variations in respiration of the patient to determine when the patient is inhaling;

delivering supplemental oxygen from an oxygen source to the patient through a supplemental oxygen delivery device when the patient is inhaling if the measured blood oxygen content level is below a desired value; and

restricting the delivery of supplemental oxygen to the patient through the supplemental oxygen delivery device if the measured blood oxygen content level of the patient is above the desired value.

14. A method according to claim 13, wherein the measured blood oxygen content level is obtained using a pulse oximeter and further wherein the method comprises:

determining if the blood oxygen content measured by the pulse oximeter is invalid;

delivering a default amount of supplemental oxygen to the patient when the measured blood oxygen content level is invalid.

15. A method of controlling supplemental oxygen delivery for sub-acute care comprising:

continuously measuring blood oxygen content of a patient to obtain a measured blood oxygen content level;

delivering a variable dose of supplemental oxygen from an oxygen source to the patient when the patient is inhaling, wherein the variable dose is at least partially determined based on the measured blood oxygen content level.

16. A method according to claim 15, wherein the variable dose of supplemental oxygen is at least partially based on a difference between the desired value for the measured blood oxygen content and the measured blood oxygen content.

17. A method according to claim 16, wherein the variable dose of supplemental oxygen is at least partially based on a trend in measured blood oxygen content as measured at different times.

18. A method according to claim 15, wherein the variable dose includes a zero dose.

19. A method according to claim 15, wherein the supplemental oxygen is delivered through a supplemental oxygen delivery device.

20. A method according to claim 19, wherein the supplemental oxygen delivery device comprises a nasal cannula.

21. A method according to claim 15, further comprising sensing variations in respiration of the patient to determine when the patient is inhaling.

22. A method according to claim 21, wherein the sensing comprises sensing when the patient is inhaling.

23. A method according to claim 21, wherein the sensing is performed using a flow sensor.

24. A method according to claim 23, wherein the flow sensor comprises a bidirectional flow sensor.

25. A method according to claim 15, wherein the method is performed in a residential setting.

26. A method according to claim 15, wherein the desired value for the measured blood oxygen content level is about 90%.

27. A method according to claim 15, wherein the measured blood oxygen content level is obtained using a pulse oximeter.

28. A method according to claim 15, further comprising:

determining if the measured blood oxygen content level is invalid;

delivering a default amount of supplemental oxygen to the patient when the measured blood oxygen content level is invalid.

29. A method of controlling supplemental oxygen delivery for sub-acute care comprising:

continuously measuring blood oxygen content of a patient to obtain a measured blood oxygen content level;

sensing variations in respiration of the patient to determine when the patient is inhaling;

delivering a variable dose of supplemental oxygen from an oxygen source to the patient through a supplemental oxygen delivery device when the patient is inhaling, wherein the variable dose of supplemental oxygen is at least partially based on a difference between the desired value for the measured blood oxygen content level and the measured blood oxygen content level.

30. A method according to claim 29, wherein the variable dose of supplemental oxygen is at least partially based on a trend in measured blood oxygen content level as measured at different times.

31. A method according to claim 29, wherein the variable dose includes a zero dose.

32. A method according to claim 29, wherein the measured blood oxygen content level is obtained using a pulse oximeter and further wherein the method comprises:

determining if the blood oxygen content level obtained by the pulse oximeter is invalid;

delivering a default amount of supplemental oxygen to the patient when the measured blood oxygen content level is invalid.

33. A method of sensing variations in respiration of a patient comprising:

providing a flow sensor in fluid communication with the respiratory flow of a patient;

monitoring the flow sensor to determine when the patient is inspiring air; and

monitoring the flow sensor to determine when the patient is expiring air.

34. A method according to claim 33, wherein the flow sensor comprises a bi-directional flow sensor.

35. A method according to claim 33, wherein the flow sensor is monitored to determine when the patient is inspiring air only after the patient has expired air.

36. A demand delivery method for controlling the delivery of oxygen to a patient comprising:

providing a flow sensor in fluid communication with the respiratory flow of a patient;

monitoring the flow sensor to determine when the patient is inhaling;

delivering oxygen to the patient when the patient is inhaling;

monitoring the flow sensor to determine when the patient is exhaling;

restricting delivery of oxygen to the patient when the patient is exhaling.

37. A system for delivering supplemental oxygen for sub-acute care, the system comprising:

a blood oxygen content level sensor;

a source of supplemental oxygen;

a valve in fluid communication with the source of supplemental oxygen; and

a controller capable of operating the valve, the controller restricting flow through the valve when the blood oxygen content level measured by the blood oxygen content level sensor is above a desired value.

38. A system according to claim 37, further comprising a supplemental oxygen delivery device attached to a patient, the supplemental oxygen delivery device in fluid communication with the valve.

39. A system according to claim 38, wherein the supplemental oxygen delivery device comprises a nasal cannula.

40. A system according to claim 37, further comprising a respiration sensor, the respiration sensor operatively connected to the controller.

41. A system according to claim 40, wherein the respiration sensor comprises a flow sensor.

42. A system according to claim 41, wherein the flow sensor comprises a bidirectional flow sensor.

43. A system according to claim 37, wherein the blood oxygen content level sensor comprises a continuous blood oxygen content level sensor.

44. A system according to claim 37, wherein the blood oxygen content level sensor comprises a pulse oximeter.

45. A system for controlling supplemental oxygen delivery comprising:

means for measuring blood oxygen content level of a patient;

means for delivering supplemental oxygen from an oxygen source to the patient when the patient is inhaling if the measured blood oxygen content level is below a desired level; and

means for restricting the delivery of supplemental oxygen from the oxygen source to the patient if the measured blood oxygen content of the patient is above a desired level.

46. A system according to claim 45, wherein the means for restricting the delivery of supplemental oxygen comprises means for preventing the delivery of supplemental oxygen.

47. A system according to claim 45, further comprising means for determining when the patient is inhaling.

48. A system according to claim 47, wherein the means for determining when the patient is inhaling comprises means for sensing variations in respiration of the patient.

49. A system according to claim 47, wherein the means for determining when the patient is inhaling comprises means for sensing the direction of respiratory airflow of the patient.

50. A system according to claim 45, wherein the means for measuring blood oxygen content level comprises means for continuously measuring blood oxygen content level.

51. A system according to claim 45, further comprising:

means for determining if the measured blood oxygen content is invalid;

means for delivering a default amount of supplemental oxygen to the patient when the measured blood oxygen content is invalid.

52. A system for controlling supplemental oxygen delivery comprising:

means for measuring blood oxygen content level of a patient; and

means for delivering a variable dose of supplemental oxygen from an oxygen source to the patient when the patient is inhaling, wherein the variable dose is at least partially determined based on the measured blood oxygen content.

53. A system according to claim 52, wherein the means for delivering a variable dose of supplemental oxygen comprises a means for determining the variable dose at least partially based on a difference between the desired value for the measured blood oxygen content level and the measured blood oxygen content level.

54. A system according to claim 52, wherein the means for delivering a variable dose of supplemental oxygen comprises a means for determining the variable dose at least partially based on a trend in measured blood oxygen content level as measured at different times.

55. A system according to claim 52, further comprising means for determining when the patient is inhaling.

56. A system according to claim 55, wherein the means for determining when the patient is inhaling comprises means for sensing variations in respiration of the patient.

57. A system according to claim 55, wherein the means for determining when the patient is inhaling comprises means for sensing the direction of respiratory airflow of the patient.

58. A system according to claim 52, wherein the means for measuring blood oxygen content level comprises means for continuously measuring blood oxygen content level.

59. A system according to claim 52, further comprising:

means for determining if the measured blood oxygen content is invalid;

means for delivering a default amount of supplemental oxygen to the patient when the measured blood oxygen content is invalid.

FIG. 1

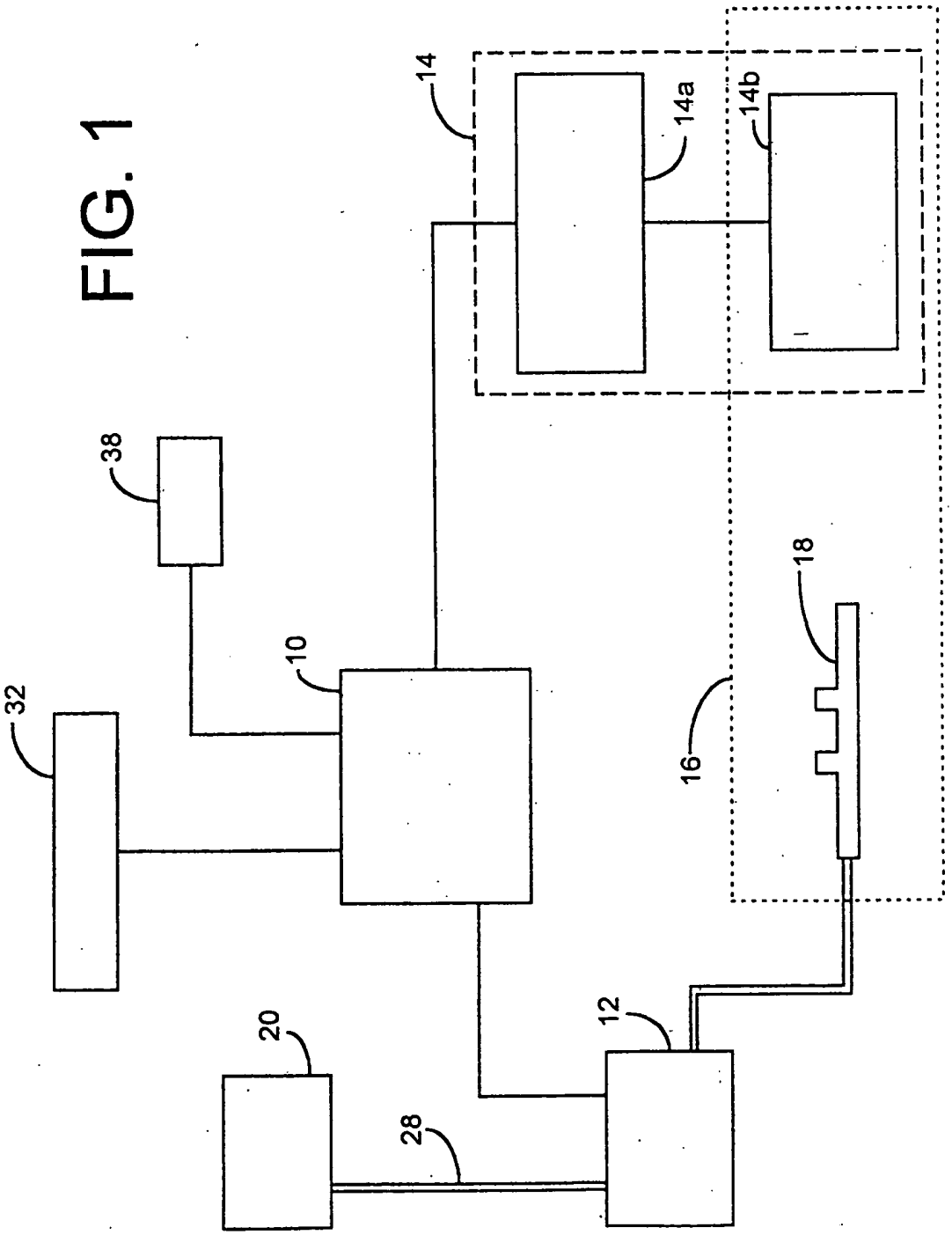
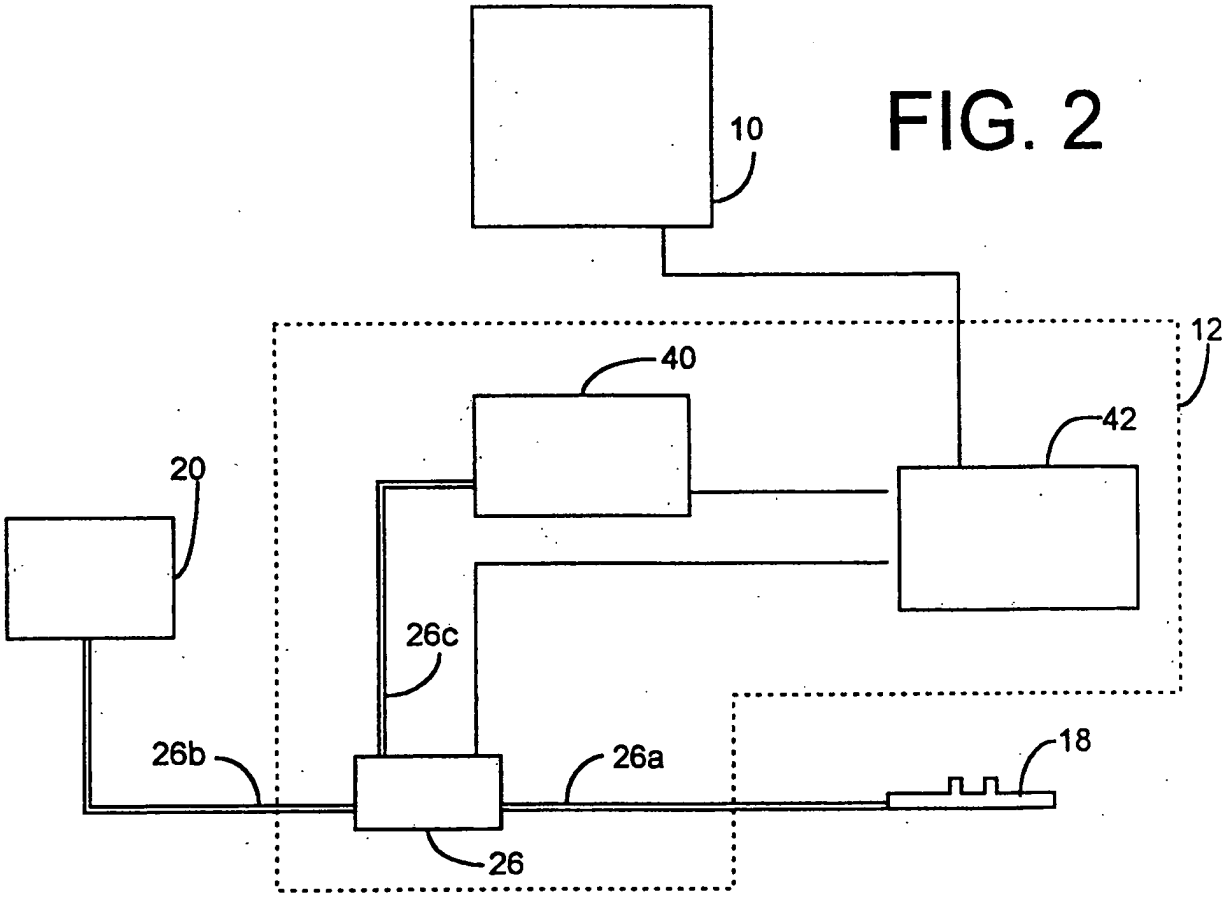


FIG. 2



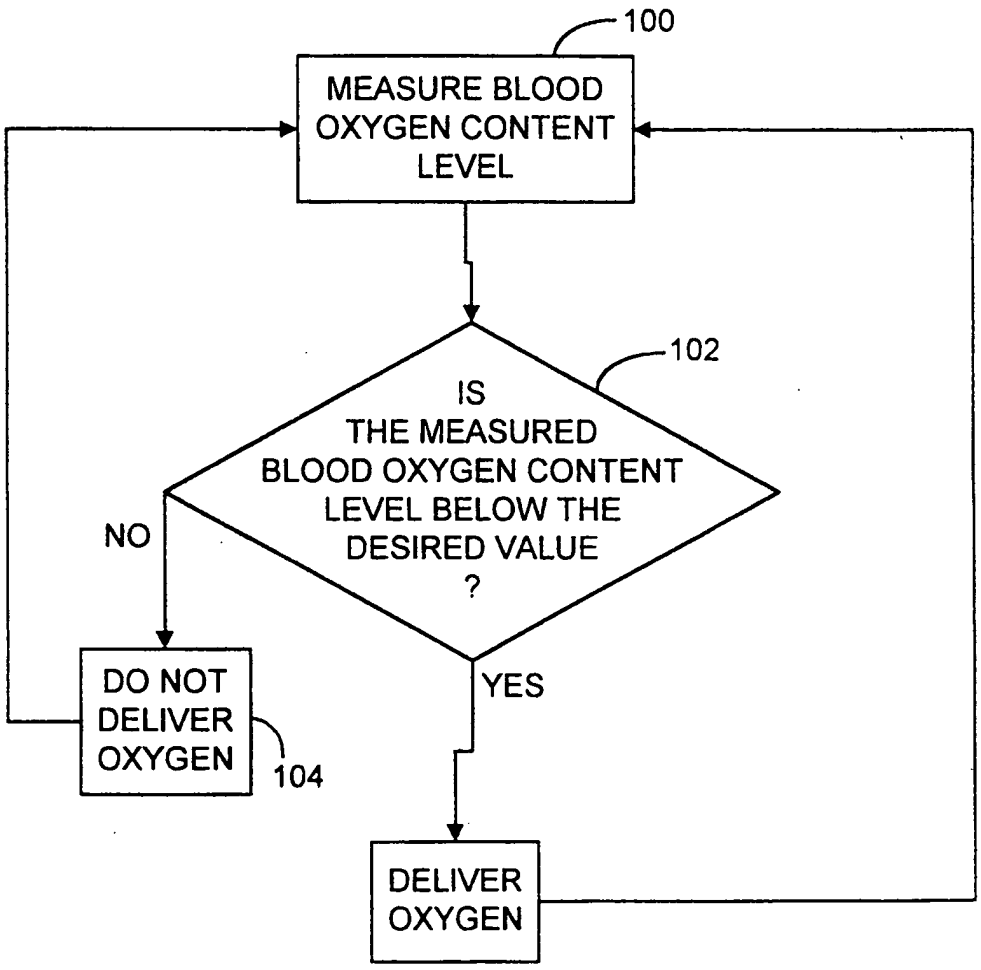

100
MEASURE BLOOD OXYGEN CONTENT LEVEL
102
IS THE MEASURED BLOOD OXYGEN CONTENT LEVEL BELOW THE DESIRED VALUE ?
NO
YES
DO NOT DELIVER OXYGEN
104
DELIVER OXYGEN

FIG. 3a

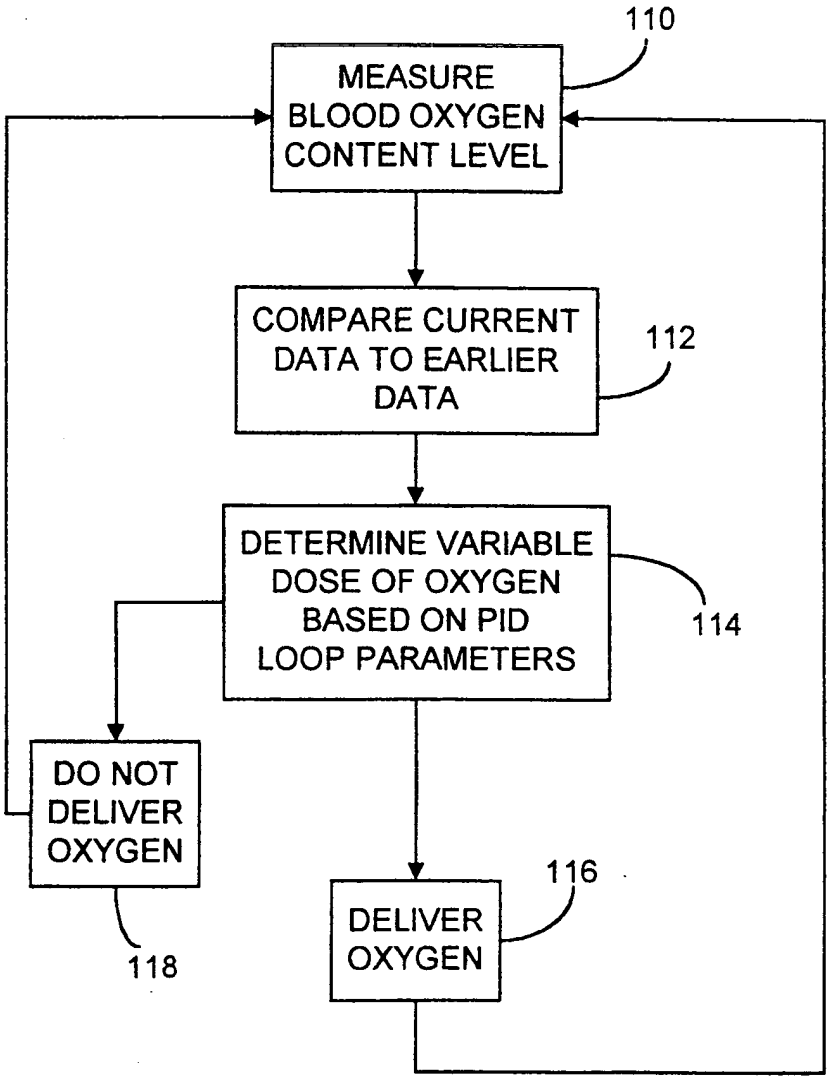

110
MEASURE BLOOD OXYGEN CONTENT LEVEL
COMPARE CURRENT DATA TO EARLIER DATA
112
DETERMINE VARIABLE DOSE OF OXYGEN BASED ON PID LOOP PARAMETERS
114
DO NOT DELIVER OXYGEN
118
DELIVER OXYGEN
116

FIG. 3b

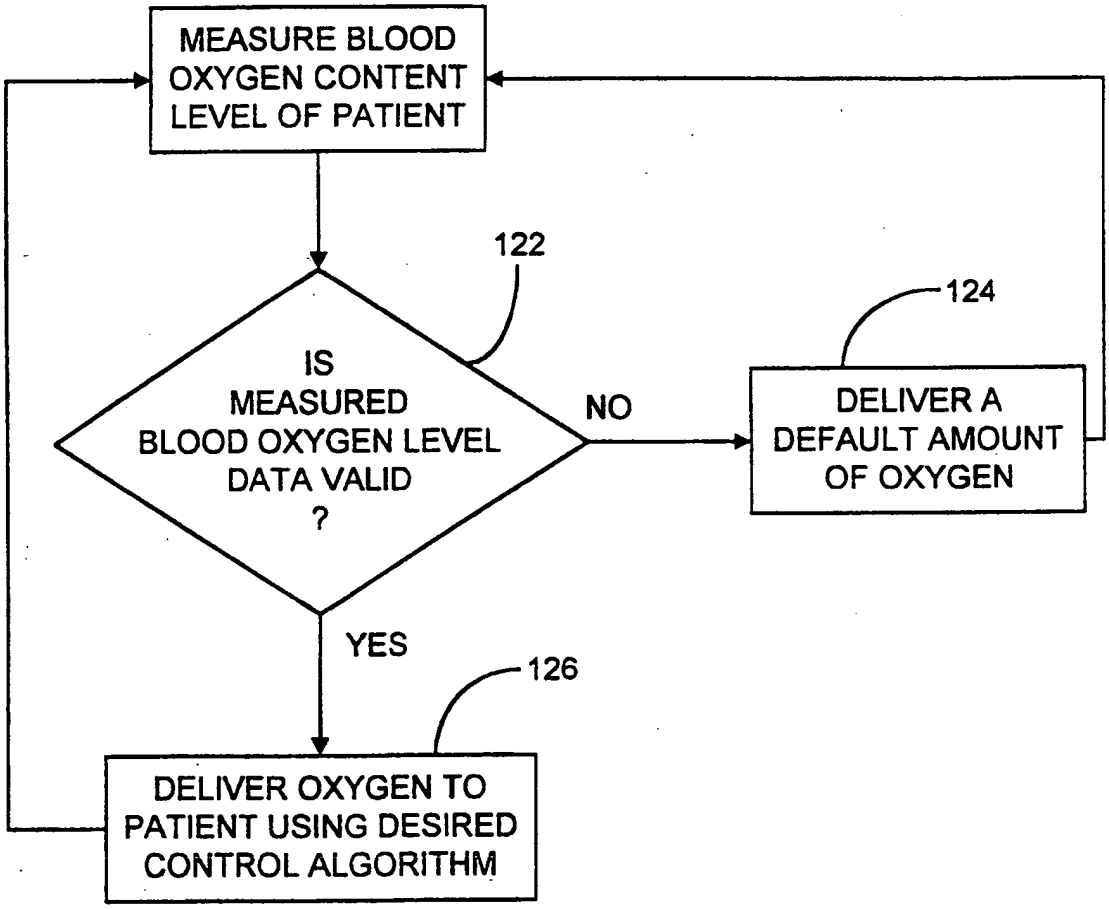

MEASURE BLOOD OXYGEN CONTENT LEVEL OF PATIENT
122
IS MEASURED BLOOD OXYGEN LEVEL DATA VALID ?
NO
124
DELIVER A DEFAULT AMOUNT OF OXYGEN
YES
126
DELIVER OXYGEN TO PATIENT USING DESIRED CONTROL ALGORITHM

FIG. 4

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 98/15490

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M16/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	EP 0 606 687 A (PURITAN BENNETT CORP) 20 July 1994 see abstract; figures 1-3 see column 3, line 21 - column 6, line 5 ---	33-35 40-42, 47-49, 52-58
X	US 4 648 395 A (SATO TORU ET AL) 10 March 1987 see abstract; figures see column 6, line 42 - line 55 see column 9, line 1 - column 10, line 12 see column 11, line 26 - line 34 see column 12, line 11 - line 23 --- -/--	33-35

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
21 December 1998	06.01.99

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Zeinstra, H

Int. ational Application No
PCT/US 98/15490

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication,where appropriate. of the relevant passages	Relevant to claim No.
X	EP 0 099 283 A (FRANCE PROD OXYGENES CO) 25 January 1984 see abstract; figure 1 see page 2, line 36 - page 4, line 18	33-35
X Y	DE 43 09 923 A (BOESCH WILHELM ;WUERTEMBERGER GEBHARD DR (DE)) 29 September 1994 see abstract; figures see column 5, line 42 - column 7, line 12	37-39, 43-46,50 40-42, 47-49, 52-58

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 98/ 15490

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 1-12,13-14,15-28,29-32, 36
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy.

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. Claims: 33-35
Method of sensing variations in respiration of a patient.

2. Claims: 37-44,45-51,52,59
System for controlling supplemental oxygen delivery.

1. [X] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[X] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 98/15490

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0606687 A	20-07-1994	US 5438980 A	08-08-1995
		AU 669237 B	30-05-1996
		AU 5262893 A	21-07-1994
		AU 697929 B	22-10-1998
		AU 6420096 A	31-10-1996
		CA 2112884 A	13-07-1994
		DE 606687 T	14-06-1995
		JP 7047126 A	21-02-1995
		US 5630411 A	20-05-1997
US 4648395 A	10-03-1987	JP 1448149 C	11-07-1988
		JP 59008972 A	18-01-1984
		JP 62054023 B	12-11-1987
EP 0099283 A	25-01-1984	FR 2530148 A	20-01-1984
		AT 21628 T	15-09-1986
		CA 1197302 A	26-11-1985
		JP 59077864 A	04-05-1984
		JP 63049512 B	04-10-1988
		US 4567888 A	04-02-1986
DE 4309923 A	29-09-1994	NONE	

Office Action Summary	Application No.	Applicant(s)	
	10/643,016	STAHMANN ET AL.	
	Examiner	Art Unit	
	Karen E. Toth	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-104* is/are pending in the application.

4a) Of the above claim(s) *5,7-13,15-19,46-49,51,63,64,73 and 75-80* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6,14,20-45,50,52-62,65-72,74 and 81-104* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/3/05, 7/12/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,016	08/18/2003	Jeffrey E. Stahmann	GUID.088PA	2956

51294 7590 06/29/2007
HOLLINGSWORTH & FUNK, LLC
8009 34TH AVE S.
SUITE 125
MINNEAPOLIS, MN 55425

EXAMINER	
TOTH, KAREN E	

ART UNIT	PAPER NUMBER
3735	

MAIL DATE	DELIVERY MODE
06/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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06/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

3. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

4. Claims 1-4, 6, 14, 20-45, 50, 52-62, 65-72, 74, and 81-104 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-40 and 80-100 of copending Application No. 10/643154 (US Patent Application Publication 2005/0043772). This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

DETAILED ACTION

Election/Restrictions

1. Claims 5, 7-13, 15-19, 46-49, 51, 63, 64, 73, and 75-80 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11 May 2007.

2. Applicant's election with traverse of claims 1-4, 6, 14, 20-45, 50, 52-62, 65-72, 74, and 81-104 in the reply filed on 11 May 2007 is acknowledged. The traversal is on the ground(s) that the designated species are not distinct, and that there is no burden on the examiner. This is not found persuasive because Applicant's arguments and examples of species overlap differ from the examiner's delineation of which claims are generic and which belong to various species. Specifically, Applicant uses "patient history" as a criteria overlapping several species as a reason they cannot be different species. Examiner designated claims directed to patient history as generic (for example, claim 80), and Applicant omitted such claims from their listing of what they believe to be generic. The arguments are therefore spurious. Applicant also has indicated that examination of all claims would not be impose a serious burden – Examiner disagrees, since examination of 104 claims directed to 13 different species would impose a very serious burden.

The requirement is still deemed proper and is therefore made FINAL.

Double Patenting

comparison, wherein the comparing and predicting are performed implantably (paragraphs [0016], [0033]-[0035], [0038]).

Regarding claim 52, Mazar discloses the detected condition comprising a first type of disordered breathing, and the prediction being that of a second type of disordered breathing (paragraph [0008]).

Regarding claims 56-60 and 66, Mazar discloses an automated method for predicting disordered breathing comprising detecting a precursor respiratory condition associated with an impending onset of disordered breathing, comparing the condition to a set of prediction criteria associated with disordered breathing, and predicting the disordered breathing based on the comparison, where the comparing and predicting are performed at least in part implantably (paragraphs [0016], [0033]-[0035], [0038]).

Regarding claims 68, 69, 72, and 74, Mazar discloses a device comprising a detector system configured to detect conditions associated with disordered breathing and comprising an implantable sensor; and a prediction engine coupled to the detector system and configured to compare the detected conditions to one or more sets of prediction criteria and predict the disordered breathing based on the comparison, wherein the prediction engine includes an implantable component (paragraphs [0016], [0033]-[0035], [0038]).

Regarding claims 71, 81, 82, 90, and 95-97, Mazar further discloses a patient input device, a network-accessible component, and a wirelessly connected component (paragraph [0044]), as well as a data storage unit (element 701; paragraph [0043]) and a display unit (paragraphs [0082]-[0083], [0088]).

6. Claims 1-4, 6, 14, 25, 35, 38-45, 49, 68, 69, 71, 72, 74, 81, 82, 90, 95, 97 are rejected under 35 U.S.C. 102(e) as being anticipated by Mazar (US Patent Application Publication 2004/0133079).

Regarding claims 1-4, 6, 14, 25, 35, and 38 Mazar discloses a method for predicting disordered breathing comprising detecting a physiological (respiratory quality) condition associated with disordered breathing, comparing the condition to one or more sets of disordered breathing prediction criteria, predicting the disordered breathing based on the comparison, and collecting data on the predictions and conditions, where the comparing and predicting are performed at least implantably (paragraphs [0016], [0033]-[0035], [0038]).

Regarding claims 33 and 34, since Mazar discloses prediction of a disordered breathing episode, Mazar discloses that "disordered breathing will occur during a particular time interval" and in "real-time".

Regarding claims 39 and 40, Mazar further discloses collecting data on the predictions, transmitting it to a separate device, and displaying it (paragraphs [0043]-[0044]).

Regarding claims 41-45, 49, and 53 Mazar discloses a method for predicting disordered breathing comprising detecting physiological or respiratory condition predisposing a patient to disordered breathing, comparing the one or more predisposing conditions to one or more sets of prediction criteria associated with disordered breathing, and predicting the disordered breathing in real time based on the

7. Claims 1-4, 6, 14, 20-22, 26, 28, 35, 38, 41-45, and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Scheiner (US Patent 6415183).

Regarding claims 1-4, 6, 14, 35, and 38 Scheiner discloses a method for predicting disordered breathing comprising detecting a physiological (respiratory quality) condition associated with disordered breathing, comparing the condition to one or more sets of disordered breathing prediction criteria, predicting the disordered breathing based on the comparison, and collecting data on the predictions and conditions, where the comparing and predicting are performed at least implantably (column 5, lines 31-39 and 44-62; column 6, lines 8-13, 53-54, and 57-65).

Regarding claims 20 and 21, Scheiner further discloses the prediction criteria comprising a threshold and comparing the sensed criteria to the threshold (column 7, lines 21-27; column 8, lines 8-32).

Regarding claim 22, Scheiner further discloses comparing a relationship between two prediction criteria to a relationship criterion that corresponds to an onset of disordered breathing (figure 5).

Regarding claims 26 and 28, Scheiner further discloses establishing and adjusting a particular set of prediction criteria based on the conditions (column 8, lines 19-32).

Regarding claims 41-45, and 49 Scheiner discloses a method for predicting disordered breathing comprising detecting physiological or respiratory condition predisposing a patient to disordered breathing, comparing the one or more predisposing

Regarding claim 98, Mazar discloses a system comprising means for detecting one or more conditions associated with a patient's disordered breathing, means for comparing the one or more conditions to one or more sets of disordered breathing prediction criteria, and means for predicting the disordered breathing, wherein at least one of the means for comparing and the means for predicting include an implantable component (paragraphs [0016], 0033]-[0035], [0038]).

Regarding claim 101, Mazar discloses an automated system comprising means for detecting one or more conditions predisposing a patient to disordered breathing, means for comparing the one or more predisposing conditions to one or more sets of disordered breathing prediction criteria, and means for predicting the disordered breathing based on the comparison, wherein at least one of the means for comparing and the means for predicting includes an implantable component (paragraphs [0016], [0033]-[0035], [0038]).

Regarding claim 102, Mazar discloses a system for predicting disordered breathing comprising means for detecting one or more precursor conditions associated with disordered breathing, means for comparing the precursor conditions to one or more sets of disordered breathing prediction criteria, and means for predicting the disordered breathing based on the comparison, wherein at least one of the means for predicting and/or comparing includes an implantable component (paragraphs [0016], [0031]-[0035], [0038]).

Regarding claims 103 and 104, Mazar further discloses detecting both a respiratory condition and an additional physiological condition (paragraph [0016]).

conditions to one or more sets of prediction criteria associated with disordered breathing, and predicting the disordered breathing based on the comparison, wherein the comparing and predicting are performed implantably (column 5, lines 31-39 and 44-62; column 6, lines 8-13, 53-54, and 57-65).

8. Claims 1, 23, 24, 26-30, 68, 70, 83, 84, 87, and 98-100 are rejected under 35 U.S.C. 102(e) as being anticipated by Mazar'161 (US Patent Application Publication 2004/0128161).

Regarding claim 1, Mazar'161 discloses a method for predicting disordered breathing comprising detecting a condition associated with disordered breathing, comparing the condition to a set of disordered breathing prediction criteria, and predicting the disordered breathing based on the comparison, where at least one of the predicting and comparing is performed implantably (paragraphs [0027]-[0031], [0061], [0066]-[0067]).

Regarding claims 23 and 24, Mazar'161 further discloses comparing the condition to the criteria by computing an estimated probability that disordered breathing will occur based on the condition by computing a composite estimated probability score, and comparing the estimated probability to a threshold probability associated with an onset of disordered breathing (paragraphs [0076]-[0079]).

Regarding claims 26-30, Mazar'161 further discloses implantably establishing and adjusting a particular set of prediction criteria based on the condition (paragraphs

[0076]-[0078]). Though Mazar'161 does not explicitly disclose deleting a set of criteria, the evolution of criteria naturally results in discarding previous sets of criteria.

Regarding claims 68, 70, and 87, Mazar'161 discloses an automated device comprising a detector system having a patient-external sensor configured to detect conditions associated with disordered breathing and a prediction engine coupled to the detector system and configured to compare the detected conditions to one or more sets of prediction criteria and predict the disordered breathing in real time based on the comparison, where the prediction engine includes an implantable component (paragraphs [0027]-[0031], [0034], [0061], [0066]-[0067]).

Regarding claims 83, 84, Mazar further discloses that the prediction engine is configured to establish the prediction criteria based on the detected conditions, and that it may adjust the set of criteria based on the detected conditions (paragraphs [0076]-[0078]).

Regarding claims 98-100, Mazar discloses a system comprising means for detecting one or more conditions associated with a patient's disordered breathing, means for comparing the condition(s) to one or more sets of disordered breathing prediction criteria, means for predicting the disordered breathing, wherein at least one of the means for comparing and/or predicting include an implantable component, and means for establishing and adjusting a particular set of prediction criteria (paragraphs [0027]-[0031], [0034], [0061], [0066]-[0067], [0076]-[0078]).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mazar in view of Nappholz (US Patent 4702253).

Mazar discloses all the elements of the claimed invention, as described above, except for monitoring a respiratory tidal volume pattern; Mazar's method of monitoring a patient's respiration is performed using thoracic impedance. Nappholz teaches a method of monitoring a patient's tidal volumes using thoracic impedance (column 2, lines 26-53), in order to accurately monitor the patient. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed Mazar and used the thoracic impedance measurements to monitor the patient's tidal volumes, as taught by Nappholz, in order to accurately monitor the patient.

11. Claims 61 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazar in view of Park (US 6741885).

Mazar discloses all the elements of the claimed inventions, as described above, except for the monitored condition being tidal volume patterns, such as hyperventilation; Mazar also discloses that the monitoring may be performed via thoracic impedance (paragraph [0038]). Park teaches a patient monitoring method comprising using thoracic impedance to monitor a patient's respiratory characteristics, such as tidal volume and hyperventilation (column 8, line 63 to column 9 line 7; column 14 line 61 to column 15 line 12), in order to accurately monitor the patient's condition. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed Mazar and monitored the patient's tidal volume or hyperventilation, as taught by Park, in order to accurately monitor the patient's condition.

Allowable Subject Matter

12. Claims 31, 32, 36, 37, 50, 54, 55, 65, 67, 85, 86, 88, 89, and 91-94 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record fails to anticipate or make obvious the inventions of claims 31 and 85, including, *inter-alia*, predicting disordered breathing by detecting a condition and comparing the condition to criteria, where the prediction criteria may be adjusted

based on the detected condition by calculating an estimated accuracy for the particular set of prediction criteria, and adjusting the set based on the estimated accuracy.

The prior art of record fails to anticipate or make obvious the inventions of claims 32 and 86, including, *inter-alia*, predicting disordered breathing by detecting a condition and comparing the condition to criteria, where the prediction criteria may be adjusted based on the detected condition by calculating an estimated sensitivity for the particular set of prediction criteria, and adjusting the set based on the estimated sensitivity.

The prior art of record fails to anticipate or make obvious the inventions of claims 36 and 91-93, including, *inter-alia*, predicting disordered breathing by detecting a condition and comparing the condition to criteria, and also collecting data associated with the predictions comprising counting the disordered breathing predictions.

The prior art of record fails to anticipate or make obvious the inventions of claims 37 and 94, including, *inter-alia*, predicting disordered breathing by detecting a condition and comparing the condition to criteria, and also collecting data associated with the accuracy of predictions.

The prior art of record fails to anticipate or make obvious the method of claim 50, including, *inter-alia*, predicting disordered breathing by detecting a patient's snoring, comparing the snoring to a set of prediction criteria associated with disordered breathing, and predicting the occurrence of disordered breathing, where the comparing and/or predicting are done at least in part implantably.

The prior art of record fails to anticipate or make obvious the inventions of claims 54 and 88, including, *inter-alia*, predicting disordered breathing by detecting a condition

and comparing the condition to criteria, where the predicted occurrence will take place within 8 hours of the prediction.

The prior art of record fails to anticipate or make obvious the inventions of claims 55 and 89, including, *inter-alia*, predicting disordered breathing by detecting a condition and comparing the condition to criteria, where the predicted occurrence will take place the next time the patient is asleep.

The prior art of record fails to anticipate or make obvious the method of claim 65, including, *inter-alia*, predicting disordered breathing by detecting a condition and comparing the condition to criteria, where the condition is the detection of the periodicity of occurrences of the disordered breathing.

The prior art of record fails to anticipate or make obvious the method of claim 67, including, *inter-alia*, predicting disordered breathing by detecting a condition and comparing the condition to criteria, where the predicted occurrence will take place within 5 minutes of the prediction.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent 4365636 to Barker, which discloses similar a similar invention.

US Patent Application Publications 2004/0122488 and 2004/0116981 to Mazar, which disclose similar inventions.

US Patent 6580944 to Katz, which discloses a similar invention.

Notice of References Cited

Application/Control No.	Applicant(s)/Patent Under Reexamination	
10/643,016	STAHMANN ET AL.	
Examiner	Art Unit	Page 1 of 1
Karen E. Toth	3735	

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2005/0043772	02-2005	Stahmann et al.	607/042
*	B	US-2004/0133079	07-2004	Mazar et al.	600/300
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*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

US Patent 6964641 to Cho, which discloses a similar invention.

US Patent 7225013 to Geva, which discloses a similar invention.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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CHARLES A. MARMOR II
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700